Page 1251 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Leidos IDIQ Ebola Project FY16 EAC

			Posted Expenses as of 4/29/16	Estimated to Completion	Total FY16 EAC	
Direct Labor & Fringe Benefits						
Non-responsive						
Materials & Supplies						
Non-responsive						
Other Direct Costs						
Non-responsive						
	UMinn Prev IV - Gilead	TBD	-	375,000	375,000	0/6 Inv Rec'd
Non-responsive						
Capital Equipment						
5610	Capital Equipment		210,962	355,196	566,158	
	Subtotal-Capital Equipment		**$ 210,962**	**$ 355,196**	**$ 566,158**	
Indirect Costs						
300	Materials, Equip & Subs	3.30%	$ 213,318	$ 798,989	$ 1,012,307	
400	General OH	29.08%	318,741	327,361	646,102	
410	A/C OH	10.11%	110,814	113,811	224,625	
500	G&A	1.04%	96,745	290,665	387,410	
	Subtotal-Indirect Costs		**$ 739,619**	**$ 1,530,826**	**$ 2,270,444**	
	TOTAL ESTIMATED COST		**$ 9,404,028**	**$ 28,241,972**	**$ 37,646,000**	

- DOES NOT INCLUDE IMAGING PROJECT (MRI/CT MACHINES)

Leidos Subcontractor and Consultant Costs

ON IDIQ TO14

5780	Research Support	IDIQ Contract No.	Inv Through	Posted Expenses	Yet to be Invoiced	EAC	Notes:
Non-responsive							
	Uminn Prev IV - Gilead	TBD		-	375,000	375,000	0/6 Inv Rec'd; Est $750k over a full year POP
Non-responsive							

Leidos PREVAIL IV EAC for FY16

	Direct Labor & Fringe Benefits		FY16 IDIQ ER	EAC	Assumptions
	Position				**Includes project IDs:**
5311	Leidos Labor		$ -		400.075.0014.0001.585.001
110	Fringe	49.62%	-		No accrued costs
	Subtotal-Direct Labor & Fringe Benefits		**$ -**	**$ -**	
Materials & Supplies					
5420	Occupational Clothing		$ -	$ 5,000	
5430	Biologicals		-	70,000	
5440	Controlled Materials		-	-	
5450	Industrial Supplies		-	10,000	
5453	Tools&Test Devices		-	-	
5455	Cleaning Supplies		-	5,000	
5460	Lab Supplies		-	90,000	
5470	Office Supplies		-	15,000	
5472	Freight		-	50,000	
5473	Telephone/wireless		-	-	
5476	Dues		-	-	
5477	Books		-	-	
5480	Computer Hardware		-	5,000	
5481	Computer Software		-	-	
	Subtotal-Materials & Supplies		**$ -**	**$ 250,000**	
Other Direct Costs					
5511	Foreign Travel		$ -		
5512	Scientific Travel		-		
5513	Administrative Travel		-		
5514	Training		-		
5515	Recruitment		-		
5516	Relocation Expenses		-		
5519	International Health Insurance		-		
5520	FCRF Seminars		-		
5550	Registration Fees		-		
5331	Direct Labor Overtime Premium		-		
5731	Postage		-		
5721	Vehicle Parts		-		
5735	Management Supprt Allocation		-		
5760	Service Maintenance Agreements		-	-	
5762	Software Support		-	-	
5764	Relocation of Equipment		-	-	
5570	Consultants		-		
5780	Research Support Services		-		
5790	Admin Support Services		-	-	
5875	Service-Interco Workorder		-	-	
5883	Non-SBA Funded		-	-	
6450	WH Industrial Supplies		-	-	
6460	WH Lab Supplies		-	-	
6470	WH Office Supplies		-	-	
	Subtotal-ODC		**$ -**	**$ -**	
Shared Services					
5914	CMRP Support		$ -	$ -	
5928	Publications		-	-	
5970	Admin Support Charge Back		-	-	
5980	Work Orders		-	-	
	Subtotal-Shared Services		**$ -**	**$ -**	
Capital Equipment					
5610	Capital Equipment		$ -	$ 78,000	
	Subtotal-Capital Equipment		**$ -**	**$ 78,000**	
Indirect Costs					
300	Materials, Equip & Subs	3.30%	$ -	$ 10,824	
400	General OH	29.08%	-	-	
410	A/C OH	10.11%	-	-	
500	G&A	1.04%	-	3,524	
	Subtotal-Indirect Costs		**$ -**	**$ 14,348**	
	TOTAL ESTIMATED COST		**$ -**	**$ 342,348**	

Leidos IDIQ Ebola Project FY16 EAC

Direct Labor & Fringe Benefits		EAC as of 5/13 "Deep Dive"	Posted Expenses as of 7/20/16	Estimated to Completion	Current FY16 EAC	Change
Position						
Non-responsive						
Materials & Supplies						
Non-responsive						
Other Direct Costs						
Non-responsive						
UMinn Prev IV - Gilead	TBD	187,500	-	212,263	212,263	24,763
Non-responsive						

Leidos Subcontractor and Consultant Costs

ON IDIQ TO14							
5780	**Research Support**	**IDIQ Contract No.**	May EAC	Posted Expenses	Yet to be Invoiced	**EAC**	Notes:
Non-responsive							
	Uminn Prev IV - Gilead	TBD	187,500	-	212,263	212,263	0/8 Inv Rec'd; Estimate is $630k Feb '16 - May '17
Non-responsive							

Leidos Prevail IV - Liberia EAC for FY16

Direct Labor & Fringe Benefits			May ER	May 1 EAC	July ER	FY16 EAC	Assumptions
	Position						**Includes project IDs:**
5311	Leidos Labor		$ -		$ -		400.075.0014.0001.005.001
110	Fringe	49.62%	-		-		Costs as of 7/20/2016
	Subtotal-Direct Labor & Fringe Benefits		**$ -**	**$ -**	**$ -**	**$ -**	
Materials & Supplies							
5420	Occupational Clothing		$ -	$ 5,000	$ 5,708	$ 6,708	
5430	Biologicals		-	70,000	34,251	125,689	$60k order pending for IRF
5440	Controlled Materials		-	-	-	-	
5450	Industrial Supplies		-	10,000	597	2,000	
5453	Tools&Test Devices		-	-	-	-	
5455	Cleaning Supplies		-	5,000	141	1,000	
5460	Lab Supplies		-	90,000	28,799	46,233	
5470	Office Supplies		-	15,000	3,248	6,000	
5472	Freight		-	50,000	32,028	50,000	
5473	Telephone/wireless		-	-	-	-	
5476	Dues		-	-	-	-	
5477	Books		-	-	-	-	
5480	Computer Hardware		-	5,000	1,955	6,761	
5481	Computer Software		-	-	4,389	4,389	
	Subtotal-Materials & Supplies		**$ -**	**$ 250,000**	**$ 111,115**	**$ 248,779**	
Other Direct Costs							
5511	Foreign Travel		$ -				
5512	Scientific Travel		-				
5513	Administrative Travel		-				
5514	Training		-				
5515	Recruitment		-				
5516	Relocation Expenses		-				
5519	International Health Insurance		-				
5520	FCRF Seminars		-				
5550	Registration Fees		-				
5331	Direct Labor Overtime Premium		-				
5731	Postage		-				
5721	Vehicle Parts		-				
5735	Management Supprt Allocation		-				
5760	Service Maintenance Agreements		-	-			
5762	Software Support		-	-	5		
5764	Relocation of Equipment		-	-			
5570	Consultants		-				
5780	Research Support Services		-				
5790	Admin Support Services		-	-			
5875	Service-Interco Workorder		-	-			
5883	Non-SBA Funded		-	-			
6450	WH Industrial Supplies		-	-			
6460	WH Lab Supplies		-	-			
6470	WH Office Supplies		-	-			
	Subtotal-ODC		**$ -**	**$ -**	**$ 5**	**$ -**	
Capital Equipment							
5610	Capital Equipment		$ -	$ 78,000	$ -	$ 78,000	$35k pending for Ace alera
	Subtotal-Capital Equipment		**$ -**	**$ 78,000**	**$ -**	**$ 78,000**	
Indirect Costs							
300	Materials, Equip & Subs	3.30%	$ -	$ 10,824	$ 3,667	$ 10,784	
400	General OH	29.08%	-	-	-	-	
410	A/C OH	10.11%	-	-	-	-	
500	G&A	1.04%	-	3,524	1,194	3,511	
	Subtotal-Indirect Costs		**$ -**	**$ 14,348**	**$ 4,861**	**$ 14,294**	
	TOTAL ESTIMATED COST		**$ -**	**$ 342,348**	**$ 115,981**	**$ 341,074**	

Consolidated Leidos Projected Requirements for the Ebola Project in West Africa

For the Period FY16 - FY20

Leidos	FY16 EAC	FY17	FY18	FY19	FY20	Total
Non-responsive						
Subtotal - Prev III	**$ 15,139,314**	**$ 14,335,601**	**$ 16,180,946**	**$ 16,420,461**	**$ 15,712,084**	**$ 77,788,406**
Prevail IV - Gilead Study	**$ 2,907,704**	**$ 1,100,797**	**$ 361,660**	**$ -**	**$ -**	**$ 4,370,161**
Variable	1,821,905	669,946	195,986	-	-	2,687,837
Fixed	1,085,799	430,851	165,674	-	-	1,682,324
Subtotal - Prev IV	**$ 2,907,704**	**$ 1,100,797**	**$ 361,660**	**$ -**	**$ -**	**$ 4,370,161**
Non-responsive						

Leidos IDIQ Ebola Project Fixed Costs

			Total FY16 EAC	FY17	FY18	FY19	FY20
Direct Labor & Fringe Benefits							
	Position						Non-respons
5311	Leidos Labor		$ 2,238,781	$ 2,286,453	$ 1,849,872	$ 1,767,624	ive
110	Fringe	49.62%	1,110,883	1,132,937	915,502	872,853	
	Subtotal-Direct Labor & Fringe Benefits		**$ 3,349,665**	**$ 3,419,390**	**$ 2,765,373**	**$ 2,640,477**	
Materials & Supplies							
5420	Occupational Clothing		$ 204	$ 204	$ 204	$ 204	
5430	Biologicals		777	777	777	777	
5440	Controlled Materials		-	-	-	-	
5450	Industrial Supplies		20,000	20,000	20,000	10,000	
5453	Tools&Test Devices		-	-	-	-	
5455	Cleaning Supplies		200	200	200	200	
5460	Lab Supplies		2,000	2,000	2,000	2,000	
5470	Office Supplies		40,000	40,000	40,000	20,000	
5472	Freight		39,805	20,903	30,759	12,863	
5473	Telephone/wireless		45,801	78,516	78,516	58,887	
5476	Dues		150	750	300	300	
5477	Books		-	-	-	-	
5480	Computer Hardware		24,875	24,875	24,875	15,000	
5481	Computer Software		-	-	-	-	
	Subtotal-Materials & Supplies		**$ 173,812**	**$ 188,225**	**$ 197,631**	**$ 120,231**	
Other Direct Costs							
5511	Foreign Travel		$ 1,247,869	$ 896,893	$ 616,515	$ 474,873	
5512	Scientific Travel		15,880	5,000	5,000	5,000	
5513	Administrative Travel		18,309	18,309	18,309	6,000	
5514	Training		-	-	-	-	
5515	Recruitment		3,846	4,000	4,000	2,000	
5516	Relocation Expenses		-	5,000	5,000	-	
5519	International Health Insurance		68,681	74,431	74,431	74,431	
5520	FCRF Seminars		-	-	-	-	
5550	Registration Fees		-	-	-	-	
5331	Direct Labor Overtime Premium		11,902	12,000	8,000	6,000	
5731	Postage		23	-	-	-	
5721	Vehicle Parts		-	-	-	-	
5735	Management Supprt Allocation		-	-	-	-	
5760	Service Maintenance Agreements		-	-	-	-	
5762	Software Support		3,000	3,000	3,000	1,500	
5764	Relocation of Equipment		-	-	-	-	
5570	Consultants		-	-	-	-	
5780	Research Support Services (TMG)	16X055Q	6,923,086	6,923,086	6,923,086	6,923,086	
5790	Admin Support Services		-	-	-	-	
5875	Service-Interco Workorder		-	-	-	-	
5883	Non-SBA Funded		-	-	-	-	
6450	WH Industrial Supplies		1,000	-	-	-	
6460	WH Lab Supplies		1,000	-	-	-	
6470	WH Office Supplies		1,600	-	-	-	
	Subtotal-ODC		**$ 8,296,195**	**$ 7,941,719**	**$ 7,657,341**	**$ 7,492,890**	
Capital Equipment							
5610	Capital Equipment		-	-	-	-	
	Subtotal-Capital Equipment		**$ -**	**$ -**	**$ -**	**$ -**	
Indirect Costs							
300	Materials, Equip & Subs	3.30%	$ 234,297	$ 239,752	$ 245,056	$ 247,273	
400	General OH	29.08%	651,038	658,270	527,213	498,647	
410	A/C OH	10.11%	226,341	230,703	186,467	177,823	
500	G&A	1.04%	134,449	133,120	121,580	117,362	
	Subtotal-Indirect Costs		**$ 1,246,124**	**$ 1,261,845**	**$ 1,080,317**	**$ 1,041,105**	
	TOTAL ESTIMATED FIXED COSTS		**$ 13,065,796**	**$ 12,811,179**	**$ 11,700,663**	**$ 11,294,703**	
Check	Total Yearly Cost		34,989,401	32,731,729	25,542,153	23,733,856	
	Minus Fixed Costs		13,065,796	12,811,179	11,700,663	11,294,703	
	Total Variable Costs		21,923,605	19,920,550	13,841,490	12,439,154	

Based on IDIQ plus new CPMII (Hassan Aug 2016-2018)

Leidos PREVAIL IV - Liberia Budget FY16-FY20

			FY16 EAC	FY17	FY18	FY19	FY20	Assumptions
Direct Labor & Fringe Benefits								
	Position							**Includes project IDs:**
5311	Leidos Labor							
110	Fringe							
	Subtotal-Direct Labor & Fringe Benefits		$ -	$ -	$ -	$ -	$ -	
Materials & Supplies								
5420	Occupational Clothing		$ 5,000	$ 2,250	$ -	$ -	$ -	55% decrease from 16-17
5430	Biologicals		70,000	31,500	-	-	-	based on # of visits
5440	Controlled Materials		-	-	-	-	-	
5450	Industrial Supplies		10,000	4,500	-	-	-	
5453	Tools&Test Devices		-	-	-	-	-	
5455	Cleaning Supplies		5,000	2,250	-	-	-	
5460	Lab Supplies		90,000	40,500	-	-	-	
5470	Office Supplies		15,000	6,750	-	-	-	
5472	Freight		141,941	33,542	-	-	-	
5473	Telephone/wireless		-	-	-	-	-	
5476	Dues		-	-	-	-	-	
5477	Books		-	-	-	-	-	
5480	Computer Hardware		5,000	2,250	-	-	-	
5481	Computer Software		-	-	-	-	-	
	Subtotal-Materials & Supplies		**$ 341,941**	**$ 123,542**	**$ -**	**$ -**	**$ -**	
Other Direct Costs								
5511	Foreign Travel							
5512	Scientific Travel							
5513	Administrative Travel							
5514	Training							
5515	Recruitment							
5516	Relocation Expenses							
5519	International Health Insurance							
5520	FCRF Seminars							
5550	Registration Fees							
5331	Direct Labor Overtime Premium							
5731	Postage							
5721	Vehicle Parts		-	-	-	-	-	
5735	Management Supprt Allocation		-	-	-	-	-	
5760	Service Maintenance Agreements		-	-	-	-	-	
5762	Software Support		-	-	-	-	-	
5764	Relocation of Equipment		-	-	-	-	-	
5570	Consultants		-	-	-	-	-	
5780	Research Support Services		1,274,908	466,528	187,500	-	-	
5790	Admin Support Services		14,700	-	-	-	-	
5875	Service-Interco Workorder		-	-	-	-	-	
5883	Non-SBA Funded		-	-	-	-	-	
6450	WH Industrial Supplies		-	-	-	-	-	
6460	WH Lab Supplies		-	-	-	-	-	
6470	WH Office Supplies		-	-	-	-	-	
	Subtotal-ODC		**$ 1,289,608**	**$ 466,528**	**$ 187,500**	**$ -**	**$ -**	
Capital Equipment								
5610	Capital Equipment		$ 114,000	$ 51,300	$ -	$ -	$ -	IGCE + Ace Alera
	Subtotal-Capital Equipment		**$ 114,000**	**$ 51,300**	**$ -**	**$ -**	**$ -**	
Indirect Costs								
300	Materials, Equip & Subs	3.30%	$ 57,603	$ 21,614	$ 6,450	$ -	$ -	
400	General OH	29.08%	-	-	-	-	-	
410	A/C OH	10.11%	-	-	-	-	-	
500	G&A	1.04%	18,753	6,961	2,036	-	-	
	Subtotal-Indirect Costs		**$ 76,356**	**$ 28,576**	**$ 8,486**	**$ -**	**$ -**	
	SUBTOTAL VARIABLE COSTS		**$ 1,821,905**	**$ 669,946**	**$ 195,986**	**$ -**	**$ -**	**$ 2,687,837**
Fixed Costs								
	Fixed Cost Allocation		$ 1,085,799	$ 430,851	$ 165,674	$ -	$ -	
	Subtotal-Fixed Costs		**$ 1,085,799**	**$ 430,851**	**$ 165,674**	**$ -**	**$ -**	
	TOTAL VARIABLE AND FIXED COSTS		**$ 2,907,704**	**$ 1,100,797**	**$ 361,660**	**$ -**	**$ -**	

Overhead Rates	FY16	FY17	FY18	FY19	FY20
Fringe - *applied to Direct Labor*	49.62%	49.55%	49.49%	49.38%	49.29%
MES - *applied to Total MES*	3.30%	3.37%	3.44%	3.51%	3.59%
General OH - *applied to Direct Labor*	29.08%	28.79%	28.50%	28.21%	27.94%
Applied/Clinical OH - *applied to Direct Labor supported by ADRD or*	10.11%	10.09%	10.08%	10.06%	10.04%
G&A - *applied Total Direct Costs + Fringe + M&S + All OH*	1.04%	1.05%	1.05%	1.05%	1.06%

Leidos Subcontractor and Consultant Costs

ON IDIQ TO14

5780	Research Support	IDIQ Contract No.	EAC FY16	FY17	FY18	FY19	FY20	Notes:
Non-responsive								
	Uminn Prev IV - Gilead	TBD	187,500	375,000	187,500	-	-	Per IGCE
Non-responsive								

	FY16	FY17	FY18	FY19	FY20	Notes
Non-responsive						
Prev 4 - Liberia	1,274,908	466,528	187,500	-	-	
Non-responsive						

Freight Allocation Study	FY16	FY17	FY18	FY19	FY20
Non-responsive					
Prev 4 Liberia	$ 314,000	$ 141,300	$ -	$ -	$ -
Non-responsive					

Prev	Visits FY15	FY16	FY17	FY18	FY19	FY20	Total Visits	
Non-responsive								
4	-	660	300	-			960	JFK
Non-responsive								

Leidos Non-Severable Funding

Ebola Funding for West Africa	Actual FY14	Actual FY15	Actual FY16	Actual FY17	Actual FY18	Projection FY19	Projection FY20	Projection FY21	Projection FY22	Projection FY23	Projection FY24	Projection FY25	Total
Non-responsive													
Incremental Cost Per Study													
Non-responsive													
PREVAIL IV - Liberia	-	-	571,442	659,830	389,814	161,876	-	-	-	-	-	-	1,782,963
Non-responsive													
MCM RCT in DRC	-	-	-	-	8,170	16,012,157	4,415,633	-	-	-	-	-	20,435,960
Non-responsive													
Non-responsive										(587,966)	(4,219,535)	(7,851,103)	(7,851,103)
Non-responsive													
Non-responsive							(2,057,537)	(1,667,171)					
							Non-responsive	(1,066,992)	(3,646,544)	(4,978,134)	(4,978,134)	Non-responsive	(4,978,134)
							-$2M Expires End of FY20	-$1.6M Expires End of FY22					

Leidos Non-Severable Funding

Ebola Funding for West Africa	Actual	Actual	Actual	Actual	Actual	Projection	Projection	Projection	Projection	Projection	Projection	Projection	Total
	FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23	FY24	FY25	
Non-responsive													
PREVAIL IV - Liberia	-	-	425,132	730,474	421,969	105,549	50,000	-	-	-	-	-	1,733,124
PREVAIL IV - Guinea	-	-	-	93,064	1,232,437	163,152	-	-	-	-	-	-	1,488,653
Non-responsive													
MCM RCT in DRC	-	-	-	-	8,133	8,656,267	10,003,182	-	-	-	-	-	18,667,582
Non-responsive													

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / Additional Funding Requirements IDIQ TO14
Expenses through August 30, 2019: Non-responsive
Leidos Non-Severable Ebola

Core Costs/Special Projects	FY15	FY16	FY17	FY18	FY19 EAC	FY20	Total
Non-responsive							
PREVAIL IV - Liberia	-	425,132	144,094	-	-	-	569,226
PREVAIL IV - Guinea	-	-	-	-	-	-	-
Non-responsive							

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / Additional Funding Requirements IDIQ TO33
Expenses through August 30, 2019: Non-responsive
Leidos Non-Severable Ebola

Core Costs/Special Projects	FY16	FY17	FY18	FY19 EAC	FY20	FY21	Total
Non-responsive							
Incremental Cost Per PREVAIL Study							
PREVAIL IV - Liberia	-	586,380	421,969	105,549	50,000	-	1,163,898
PREVAIL IV - Guinea	-	93,064	16,421	365	-	-	109,850
Non-responsive							

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / Additional Funding Requirements IDIQ TO43
Expenses through August 30, 2019: Non-responsive
Leidos Non-Severable Ebola

Core Costs/Special Projects	FY17	FY18	FY19 EAC	FY20	FY21	FY22	Total
Non-responsive							
PREVAIL IV - Guinea	-	1,216,016	162,787	-	-	-	1,378,803
MCM RCT - DRC (To TO59)		8,133	8,641,452	3,462,677	-	-	12,112,262
Non-responsive							

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / Additional Funding Requirements IDIQ TO59
Expenses through August 30, 2019:

Leidos Non-Severable Ebola

Base Period	FY19 EAC	FY20	FY21	FY22	FY23	Total	Base/Options Tracking Budget	Balance
Non-responsive								
Milestone 2 - Existing Studies (DRC MCM-RCT)	-	6,540,506	-	-	-	6,540,506	8,238,055	1,697,549
Non-responsive								

Page 1311 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Leidos Biomed Non-Severable Funding

Ebola Funding for West Africa & the DRC	Actual FY14	Actual FY15	Actual FY16	Actual FY17	Actual FY18	Projection FY19	Projection FY20	Projection FY21	Projection FY22	Projection FY23	Projection FY24	Total
Non-responsive												
PREVAIL IV - Liberia	-	-	425,132	730,474	421,969	105,549	-	-	-	-	-	1,683,124
PREVAIL IV - Guinea	-	-	-	93,064	1,232,437	163,152	-	-	-	-	-	1,488,653
Non-responsive												
MCM RCT in DRC	-	-	-	-	8,133	8,656,267	10,003,182	-	-	-	-	18,667,582
Non-responsive												

*No NS Funding availble past FY23

Non-responsive

EXPIRES AT THE END OF FY22: 6,800,000

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / Additional Funding Requirements IDIQ TO14
Expenses through August 30, 2019: Non-responsive
Leidos Non-Severable Ebola

Core Costs/Special Projects	FY15	FY16	FY17	FY18	FY19 EAC	FY20	Total
Non-responsive							
PREVAIL IV - Liberia	-	425,132	144,094	-	-	-	569,226
PREVAIL IV - Guinea	-	-	-	-	-	-	-
Non-responsive							
Non-responsive							$ 402,480

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / Additional Funding Requirements IDIQ TO33
Expenses through August 30, 2019: Non-responsive
Leidos Non-Severable Ebola

Non-responsive

Incremental Cost Per PREVAIL Study							
PREVAIL IV - Liberia	-	586,380	421,969	105,549	-	-	1,113,898
PREVAIL IV - Guinea	-	93,064	16,421	365	-	-	109,850

Non-responsive

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / Additional Funding Requirements IDIQ TO43
Expenses through August 30, 2019: Non-responsive
Leidos Non-Severable Ebola

Non-responsive							
PREVAIL IV - Guinea	-	1,216,016	162,787	-	-	-	1,378,803
MCM RCT - DRC (To TO59)		8,133	8,641,452	3,462,677	-	-	12,112,262
Non-responsive							
Non-responsive							6,800,000
Non-responsive							
Non-responsive							
Non-responsive							$ 6,800,000

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / Additional Funding Requirements IDIQ TO59
Expenses through August 30, 2019: Non-responsive
Leidos Non-Severable Ebola

Base Period	FY19 EAC	FY20	FY21	FY22	FY23	Total	Base/Options Tracking Budget	Balance
Non-responsive								
Milestone 2 - Existing Studies (DRC MCM-RCT)	-	6,540,506	-	-	-	6,540,506	8,238,055	1,697,549
Non-responsive								
Non-responsive						$ 17,680,783		

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
EAC Projections / IDIQ TO13
Expenses through August 30, 2019:
Leidos Non-Severable Ebola

Non-responsive

	FY16	FY17	FY18	FY19 EAC	FY20	Total
Non-responsive						

Page 1318 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

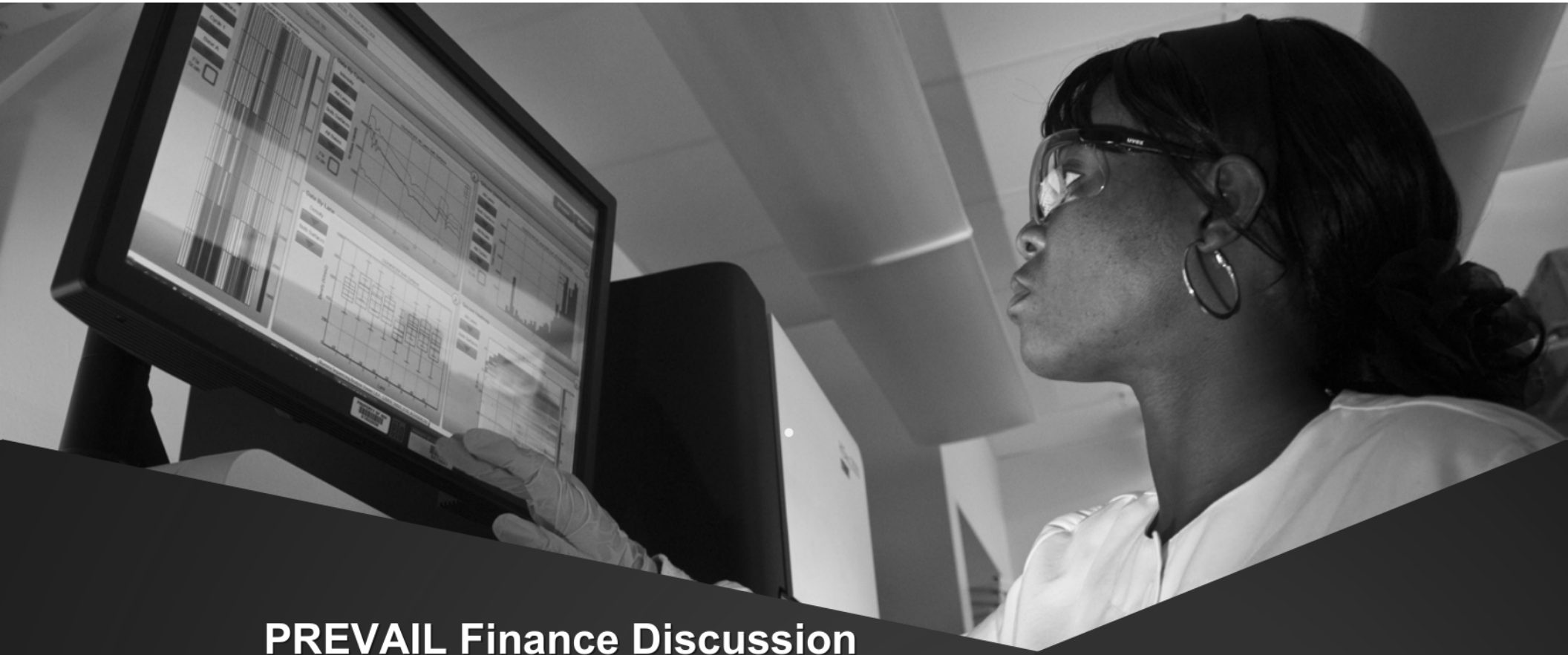
Additional Requirements Not Included in Current FY16 IDIQ Expenses:

Not included in the EAC

	Requirement	Est. Amount Outstanding	Notes:
Non-responsive			
7.)	PREVAIL IV		AMBL lab costs
8.)			
9.)			
10.)			
11.)			
12.)			
	Total Outstanding	$ 2,500,000.00	

leidos

Leidos Biomedical Research, Inc.



PREVAIL Finance Discussion

November 7, 2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES • National Institutes of Health • National Cancer Institute

Frederick National Laboratory is a Federally Funded Research and Development Center operated by Leidos Biomedical Research, Inc., for the National Cancer Institute

Agenda

Purpose This presentation outlines spend to date, spend plans against budgets, and the steps to be taken for fiscally responsible actions to approve new science and the process for managing changes to task orders. This discussion pertains to YT15-011NS, Task Order 33, Task Order 14, and Task Order 43.Review of Actuals Versus BudgetsReview of LBR Staffing, Travel and Other ExpensesReview of Subcontracts – TMG, LCP, UMN, InCadence, ABMLReview of IRF SpendingConference SupportUnanticipated ExpensesAuthority Matrix – New Science ProposalsTO43 BudgetTO43 Change Management ProcessNext StepsProposed Cost Savings Measures

Review of Actuals Versus Budgets

Page 1323 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1324 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Actuals Versus Budget Task Order 14

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
Status of IDIQ TO14

Leidos Non-Severable Ebola

Non-responsive	FY15	FY16	FY17 EAC	2018 Expenses	FY18 Encumbrances	Total
Non-responsive						
Incremental Cost Per Study						
Non-responsive						
PREVAIL IV - Liberia	-	569,150	3,164	-	-	572,313
PREVAIL IV - Guinea						-
Non-responsive						

Page 1326 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Actuals Versus Budget Task Order 33

Leidos Biomedical Research, Inc.
Clinical Monitoring Research Program
Status of IDIQ TO33

Leidos Non-Severable Ebola

Non-responsive

Non-responsive

Incremental Cost Per PREVAIL Study

Non-responsive

	FY16	FY17	FY18 Expenses	FY18 Encumbrances	Total
PREVAIL IV - Liberia	5,381	621,592	1,791	53	628,817
PREVAIL IV - Guinea	-	100,877	3	-	100,880

Non-responsive

Page 1328 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Summary Actuals Versus Budget (YT 15-011NS, TO14, TO33)

Leidos Non-Severable Ebola

Core Costs	FY14	FY15	FY16	FY17	FY18 Encumbrances	Total
Non-responsive						
Incremental Cost Per PREVAIL Study						
Non-responsive						
PREVAIL IV - Liberia	-	-	574,530	624,756	1,845	1,201,131
Non-responsive						

Task Order 43 Proposed Budget

Leidos Biomedical Research, Inc.

Clinical Monitoring Research Program

Status of IDIQ TO43

Leidos Non-Severable Ebola

Core Costs	FY17	FY18 EAC	FY19	FY20	FY21	FY21	Total
Non-responsive							
Incremental Cost Per PREVAIL Study							
PREVAIL IV - Guinea	-	1,195,247	22,093	-	-	-	1,217,340
							-
Non-responsive							

Page 1331 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1332 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1333 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1334 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1335 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1336 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1337 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1338 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1339 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1340 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Review of Subcontracts - TMG, LCP, UMN, InCadence, ABML

Subcontracts Overview

EBOLA SUBCONTRACTS

Subcontractor	Study	PO#	TPM/RC	Period of Performance	Funded Amount	Remaining Funds	Funded Through	Invoice Status	Burn Rate	# Months Funding Remaining	Month Funding Required	Funding Notes	Task Order
Non-responsive													
University of Minnesota	PREVAIL IV - Gilead - L	16X054Q5	Sara/Eileen	8/13/2016 - 12/31/2017	464,820	227	10/31/2017	Aug-17	37,061	0.01	Aug-17	POP extended as the study has been extended due to slow enrollment. Mod to request budget for P4 Guinea.	TO33
Non-responsive													

Last Updated: 11/1/2017

Non-responsive

Page 1343 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1344 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1345 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1346 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1347 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1348 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1349 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1350 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1351 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1352 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1353 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1354 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1355 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1356 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1357 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1358 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1359 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1360 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1361 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1362 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Review of IRF Costs

IRF Purchases for FY15, FY16 and FY17

Country	Clinical Trial	FY2015	FY2016	FY2017	FY2018-Q1	Grand Total
Guinea	Non-responsive					
	PREVAIL IV	$ -	-	-	15,482	$ 15,482
Guinea Total	Non-responsive					
Liberia						
	PREVAIL III, IV, VI	$ -	-	-	77	$ 77
	PREVAIL IV	$ -	60,785	659	-	$ 61,444
	Non-responsive					
Liberia Total						
U.S.A.						
	PREVAIL IV	$ -	-	6,180	6,865	$ 13,045
	Non-responsive					
Non-responsive						

Page 1365 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1366 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1367 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Unanticipated Expenses

Unanticipated Expenses

- Examples to includePREVAIL IV rural recruitments Non-responsive

Non-responsive

Page 1370 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1371 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Task Order 43 Budgeted Scope

The budget presented reflects our complete and current estimate of the cost required to complete the SOW and deliver the deliverables. This budget reflects the milestones for this work. The milestones will occur concurrently. Any new studies will be undertaken only after discussion with NIAID DCR regarding the requirements, followed by an internal assessment of resources needed for the new study and the resources remaining on this task order.Completion of Specific Pre-existing Studies Facilitate conduct, follow-up and close-out of PREVAIL IV in Guinea, Non-responsive

Non-responsive

Non-responsive

Task Order 43 Proposed Budget

Leidos Biomedical Research, Inc.

Clinical Monitoring Research Program

Status of IDIQ TO43

Leidos Non-Severable Ebola

Core Costs	FY17	FY18 EAC	FY19	FY20	FY21	FY21	Total
Non-responsive							
Incremental Cost Per PREVAIL Study							
PREVAIL IV - Guinea		- 1,195,247	22,093		-	-	- 1,217,340
							-
Non-responsive							

Page 1374 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1375 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1376 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1377 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1378 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1379 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Next Steps

Page 1381 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Page 1382 of 1425

Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

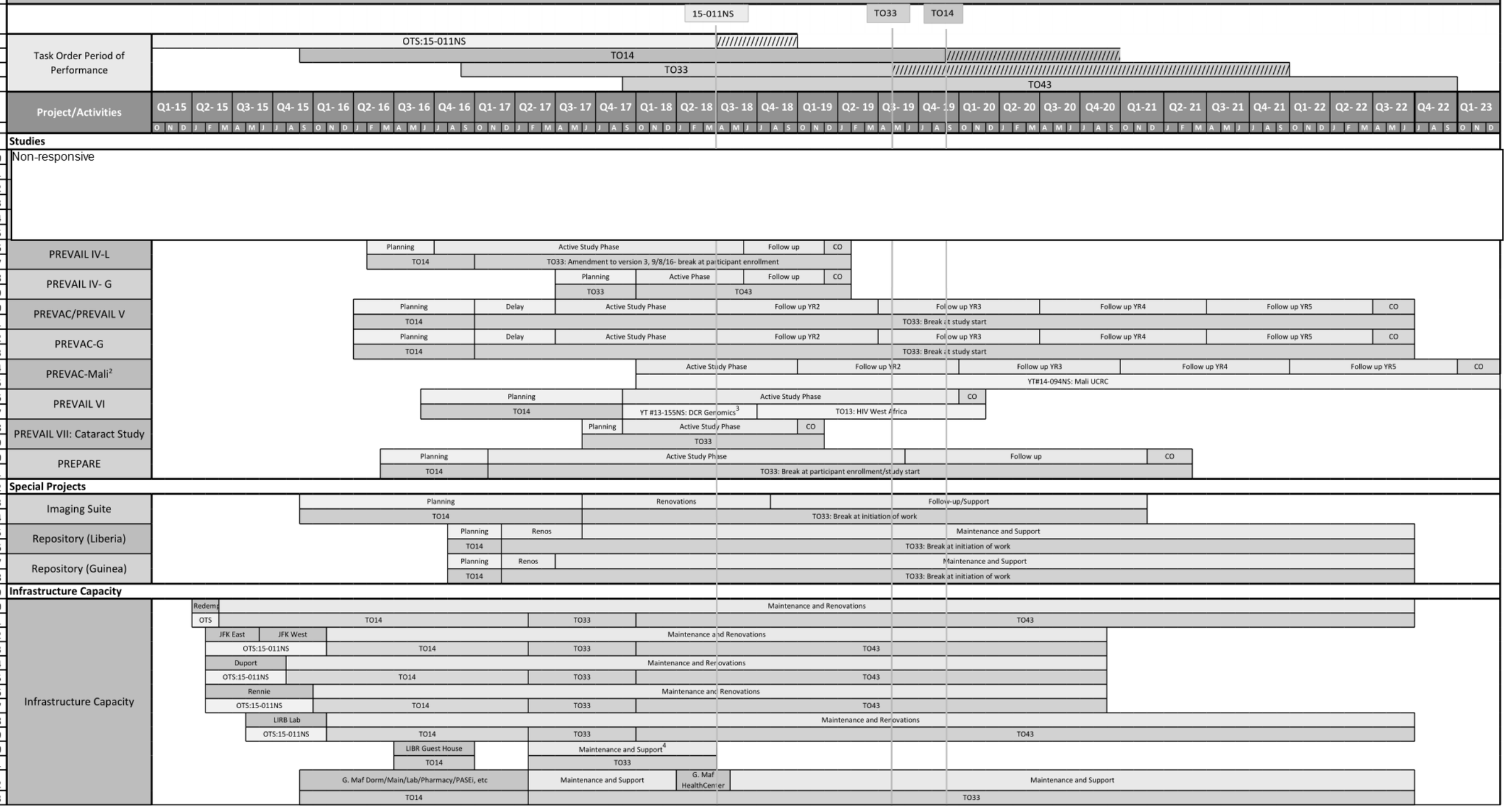
Page 1383 of 1425

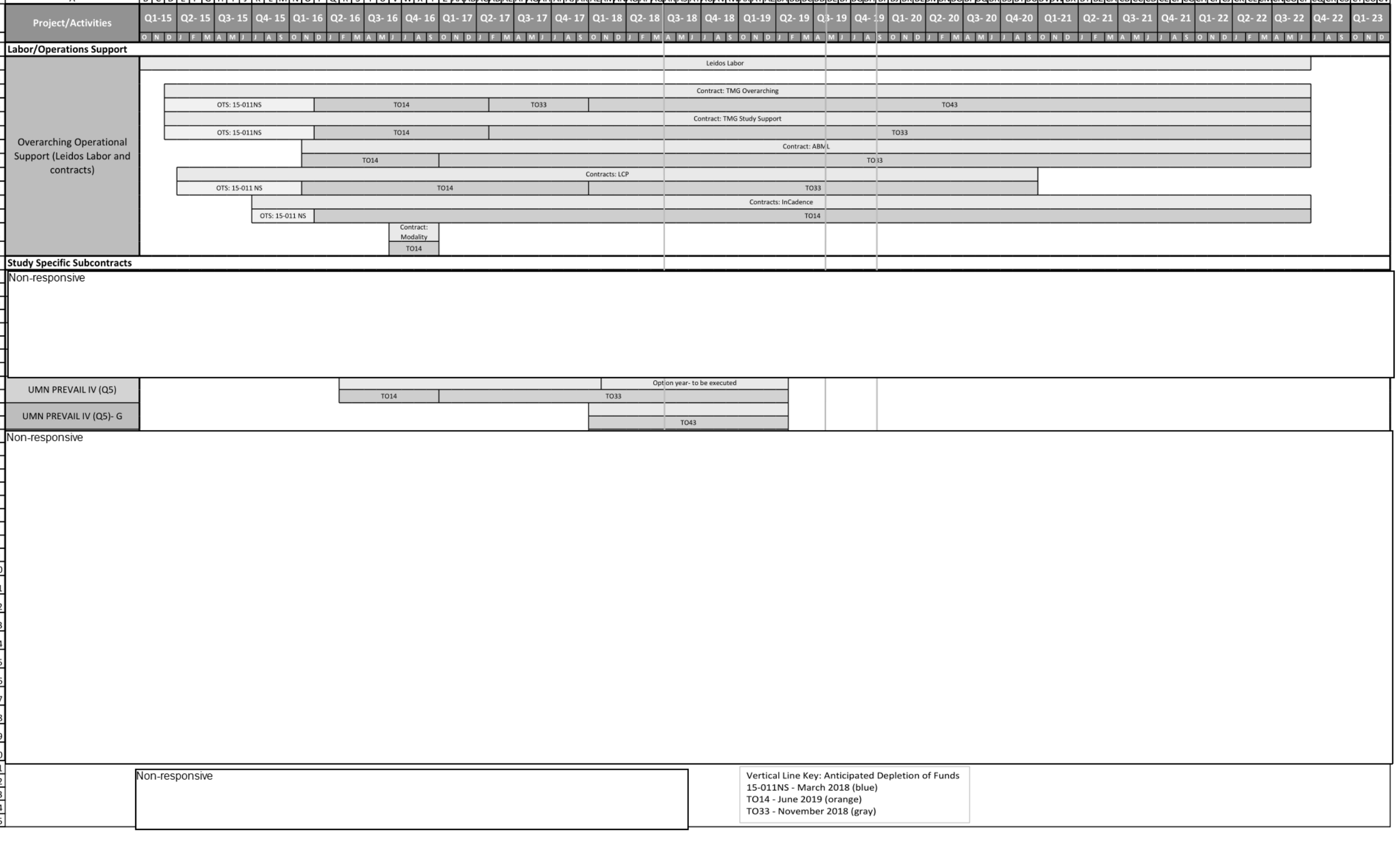
Withheld pursuant to exemption

Non-responsive

of the Freedom of Information and Privacy Act

Ebola Response Program Stategy Map




Project/Activities
Q1-15
Q2- 15
Q3- 15
Q4- 15
Q1- 16
Q2- 16
Q3- 16
Q4- 16
Q1- 17
Q2- 17
Q3- 17
Q4- 17
Q1- 18
Q2- 18
Q3- 18
Q4- 18
Q1-19
Q2- 19
Q3- 19
Q4- 19
Q1- 20
Q2- 20
Q3- 20
Q4-20
Q1-21
Q2- 21
Q3- 21
Q4- 21
Q1- 22
Q2- 22
Q3- 22
Q4- 22
Q1- 23
Labor/Operations Support
Overarching Operational Support (Leidos Labor and contracts)
Leidos Labor
Contract: TMG Overarching
OTS: 15-011NS
TO14
TO33
TO43
Contract: TMG Study Support
OTS: 15-011NS
TO14
TO33
Contract: ABMI
TO14
TO33
Contracts: LCP
OTS: 15-011 NS
TO14
TO33
Contracts: InCadence
OTS: 15-011 NS
TO14
Contract: Modality
TO14
Study Specific Subcontracts
Non-responsive
UMN PREVAIL IV (Q5)
Option year- to be executed
TO14
TO33
UMN PREVAIL IV (Q5)- G
TO43
Non-responsive
Non-responsive
Vertical Line Key: Anticipated Depletion of Funds
15-011NS - March 2018 (blue)
TO14 - June 2019 (orange)
TO33 - November 2018 (gray)

Budget Y	Project	Project N	PRIME_C	Account	L2_ACCT	TotalAM	Account I	ACCT_NU	Ledger Y	Period	Post Dt	Post Sou	Org ID	Descripti	Descripti	Descripti	SS_ITEM	Part No/	MX_ITEM	TELE_NO	FED_EX_	CSAS_ID	Vendor	PR No	Requests	Requeste	Requeste	Order Qt	Unit Cost	PO No	Release I	PO Line I	Buyer	Buyer	Vendor I	Voucher	Voucher /	Commen	Trans Amt
2018	400.875.0	Ebola PKD	HHSN26	10-5311	DIRECT L	4,289.2	10-5311	DIRECT L	2018	12	#####	LD	2.01.02	LD Posting: #####																							4,289.2
2019	400.875.0	Ebola PKD	HHSN26	10-5311	DIRECT L	#####	10-5311	DIRECT L	2019	1	#####	LD	2.01.02	LD Posting: #####																							#####
2019	400.875.0	Ebola PKD	HHSN26	10-5311	DIRECT L	#####	10-5311	DIRECT L	2019	1	#####	LD	2.01.02	LD Posting: #####																							#####
2019	400.875.0	Ebola PKD	HHSN26	10-5311	DIRECT L	#####	10-5311	DIRECT L	2019	2	#####	LD	2.01.02	LD Posting: #####																							#####
2019	400.875.0	Ebola PKD	HHSN26	15-5430	BIOLOGIC	175.61	15-5430-0	BIOLOGIC	2019	2	#####	APV	2.01.02	Concorse Plus Personal Lubricant, Pre-filled Applicators				B004QHALRK					Amazon		Direct Ship to IRF		L57451	854	1	Poole, Holly M		PC101826	10416342	PCARD Concentric		149.85
2019	400.875.0	Ebola PKD	HHSN26	15-5430	BIOLOGIC	175.61	15-5430-0	BIOLOGIC	2019	2	#####	APV	2.01.02	Purell Hand Sanitizer Alcohol Wipes, 300/pk				B0745VXZN5					AMAZON		B200 RESEARCH PLZ		L57369	855	1	Mendizabal, Jennifer '		PC101826	10416647	PCARD Concentric		25.76
2019	400.875.0	Ebola PKD	HHSN26	15-5460	LAB SUPP	2,965.85	15-5460-0	LAB SUPP	2019	1	#####	APV	2.01.02	Cadd Infusion Pump				6101					CRI		Industry Lane		L57451	839	1	Poole, Holly M		PC101806	10410406	PCARD Concentric		1,299
2019	400.875.0	Ebola PKD	HHSN26	15-5460	LAB SUPP	2,965.85	15-5460-0	LAB SUPP	2019	2	#####	APV	2.01.02	Specimen Containers with Dual Click				18803-906					VWR INTERNATIONAL INC		Direct Ship to IRF		B16108AR	192	1	Poole, Holly M		B18041928	10416861	Invoice Concentric		102.85
2019	400.875.0	Ebola PKD	HHSN26	15-5460	LAB SUPP	2,965.85	15-5460-0	LAB SUPP	2019	2	#####	APV	2.01.02	TT Ultra 16K 1.5M Plus Probe Logger				TUP12-02-003					Servaltech		HOLD FOR DRC		L57451	853	1	Poole, Holly M		PC101826	10416152	PCARD Concentric		1,440
2019	400.875.0	Ebola PKD	HHSN26	15-5460	LAB SUPP	2,965.85	15-5460-0	LAB SUPP	2019	2	#####	APV	2.01.02	6 x 9" Specimen Bags				S-23668					Uline		Direct Shipt To IRF		L57451	855	1	Poole, Holly M		PC101826	10416340	PCARD Concentric		57
2019	400.875.0	Ebola PKD	HHSN26	15-5460	LAB SUPP	2,965.85	15-5460-0	LAB SUPP	2019	2	#####	APV	2.01.02	8 x 10" Specimen Bags				S-2970					Uline		Direct Shipt To IRF		L57451	855	2	Poole, Holly M		PC101826	10416340	PCARD Concentric		67
2019	400.875.0	Ebola PKD	HHSN26	15-5470	OFFICE SU	542.07	15-5470-0	OFFICE SU	2019	2	#####	APV	2.01.02	Flip Chart Markers									STAPLES		S. FUNK / INDUSTRY LANE		L54423	675	2	Funk, Shelley A		PC101826	10416382	PCARD Concentric		70.11
2019	400.875.0	Ebola PKD	HHSN26	15-5470	OFFICE SU	542.07	15-5470-0	OFFICE SU	2019	2	#####	APV	2.01.02	Post-It Flip Charts				559-VAD-6PK					STAPLES		S. FUNK / INDUSTRY LANE		L54423	675	1	Funk, Shelley A		PC101826	10416382	PCARD Concentric		385.98
2019	400.875.0	Ebola PKD	HHSN26	15-5470	OFFICE SU	542.07	15-5470-0	OFFICE SU	2019	2	#####	APV	2.01.02	Samsung Galaxy Tab S3 keyboard Cover, Gray				BO6XSWQDHJ					AMAZON		M. SCHENDLER- IL		L57369	855	2	Mendizabal, Jennifer '		PC111800	10417488	PCARD Concentric		165.98
2019	400.875.0	Ebola PKD	HHSN26	15-5472	FREIGHT	160.68	15-5472-0	FREIGHT	2019	1	#####	APV	2.01.02	FREIGHT									CRI				L57451	839				PC101806	40410466	PCARD	PCARD-FR	59.57
2019	400.875.0	Ebola PKD	HHSN26	15-5472	FREIGHT	160.68	15-5472-0	FREIGHT	2019	2	#####	APV	2.01.02	FedEx Priority Overn	Matt Kirchoff Leidos					461158863990			FEDERAL EXPRESS CORP										LEIDOS BI	63388495	33001919	FEDEX 3rs TrackID: (		7.96
2019	400.875.0	Ebola PKD	HHSN26	15-5472	FREIGHT	160.68	15-5472-0	FREIGHT	2019	2	#####	APV	2.01.02	FREIGHT									Servaltech				L57451	853				PC101824	40416152	PCARD	PCARD-FR	11.12
2019	400.875.0	Ebola PKD	HHSN26	15-5472	FREIGHT	160.68	15-5472-0	FREIGHT	2019	2	#####	APV	2.01.02	FREIGHT									Amazon				L57451	854				PC101826	40416342	PCARD	PCARD-FR	7.76
2019	400.875.0	Ebola PKD	HHSN26	15-5472	FREIGHT	160.68	15-5472-0	FREIGHT	2019	2	#####	APV	2.01.02	FREIGHT									Uline				L57451	855				PC101826	40416340	PCARD	PCARD-FR	17.99
2019	400.875.0	Ebola PKD	HHSN26	15-5472	FREIGHT	160.68	15-5472-0	FREIGHT	2019	2	#####	APV	2.01.02	FREIGHT									AMAZON				L57369	855				PC111800	40417488	PCARD	PCARD-FR	13.7
2019	400.875.0	Ebola PKD	HHSN26	15-5472	FREIGHT	160.68	15-5472-0	FREIGHT	2019	2	#####	APV	2.01.02	FREIGHT									AMAZON				L57369	855				PC111800	40417490	PCARD	PCARD-FR	42.88
2019	400.875.0	Ebola PKD	HHSN26	15-5480	COMPUTE	1,163.16	15-5480-0	COMPUTE	2019	2	#####	APV	2.01.02	Microsoft Designer Bluetooth Mouse				B0859CTU2Y					AMAZON		M. SCHENDLER- IL		L57369	855	1	Mendizabal, Jennifer '		PC111800	10417488	PCARD Concentric		57.16
2019	400.875.0	Ebola PKD	HHSN26	15-5480	COMPUTE	1,163.16	15-5480-0	COMPUTE	2019	2	#####	APV	2.01.02	Samsung Galaxy Tab S3 SM-T825 32g, Black, Wi-Fi- Ca				B077W54BCN					AMAZON		M. SCHENDLER- IT		L57369	855	3	Mendizabal, Jennifer '		PC111800	10417490	PCARD Concentric		1,106
2019	400.875.0	Ebola PKD	HHSN26	20-5511	TRAVEL PI	1,556	20-5511-0	TRAVEL PI	2019	1	#####	APV	2.01.02	TRAVEL FOREIGN-OTHER									Profitt Jr., Calvin H										10409774	CHECKREC	CHECKRE	550
2019	400.875.0	Ebola PKD	HHSN26	20-5511	TRAVEL PI	1,556	20-5511-0	TRAVEL PI	2019	1	#####	APV	2.01.02	TRAVEL FOREIGN-OTHER									Profitt Jr., Calvin H										10411267	CHECKREC	CHECKRE	680
2019	400.875.0	Ebola PKD	HHSN26	20-5511	TRAVEL PI	1,556	20-5511-0	TRAVEL PI	2019	1	#####	APV	2.01.02	Bank Fee 10/04-10/04/18 , (TRAFOROTH / Oct 4 2018)									Profitt Jr., Calvin H										ERB00139	33001959	Bank fee f bank fee f		3
2019	400.875.0	Ebola PKD	HHSN26	20-5511	TRAVEL PI	1,556	20-5511-0	TRAVEL PI	2019	1	#####	APV	2.01.02	Bank Fees 10/10-10/10/18 , (TRAFOROTH / Oct 10 2018)									Profitt Jr., Calvin H										ERB00139	33001959	Bank Fees bank fees		3
2019	400.875.0	Ebola PKD	HHSN26	50-5785	SERVICES	4,489.5	50-5785-0	SERVICES	2019	2	#####	APV	2.01.02	Translation Services From English To Swahili				98930					TRANSPERFECT TRANSLATIONS		NO GOODS RECEIVED		R17169N	72	1	Poole, Holly M		1435989	10416573	Invoice Concentric		4,489.5

Expense Register Report

Budget Year: 2018, 2019   Ledger Year: Period(s):   Project ID Starts With: 400.073.0043.0001.004

Budget Year: 2018

Account Detail	Ledger Year - Period	Post Date / Source	Org ID	Description	Item No. Part No. Serial No. Other Id No	Vendor System	PR No	Requester	Order Qty	Unit Cost	PO No	Release No	PO Line No	Buyer	Vendor Invoice No	Voucher No	Voucher Notes	Comments/Details System Data	Trans Amt
Project Id & Name: 400.073.0043.0001.004.693.0010 Ebola MCM RCT																			
DIRECT LABOR																			[illegible]
DIRECT LABOR	[illegible]	[illegible]	[illegible]	LB Posting [illegible]															[illegible]
																		400.073.0043.0001.004.693.0010 Total	[illegible]

Budget Year: 2019

Account Detail	Ledger Year - Period	Post Date / Source	Org ID	Description	Item No. Part No. Serial No. Other Id No	Vendor System	PR No	Requester	Order Qty	Unit Cost	PO No	Release No	PO Line No	Buyer	Vendor Invoice No	Voucher No	Voucher Notes	Comments/Details System Data	Trans Amt
Project Id & Name: 400.073.0043.0001.004.693.0010 Ebola MCM RCT																			
DIRECT LABOR																			[illegible]
BIOLOGICALS																			[illegible]
LAB SUPPLIES																			[illegible]
OFFICE SUPPLIES																			[illegible]
FREIGHT																			[illegible]
COMPUTER HARDWARE																			[illegible]
TRAVEL FOREIGN																			[illegible]
SERVICES - COMMERCIAL																			[illegible]
																		400.073.0043.0001.004.693.0010 Total	[illegible]
																		Report Grand Total	[illegible]

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
			1 10

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75N91019D00024/75N91020F00010	See Block 20C	5683381

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 5)	CODE
National Institutes of Health National Cancer Institute Bldg 1050 Frederick, MD 21702	NCI-BLDG 427	National Institutes of Health National Cancer Institute Bethesda, MD 20892-7511 SCD-C	NCI

7. NAME AND ADDRESS OF CONTRACTOR (No., street, country, State and ZIP Code)	8. DELIVERY	9. DISCOUNT FOR PROMPT PAYMENT	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN	ITEM
LEIDOS BIOMEDICAL RESEARCH, INC.:1107088 P.O. BOX B FREDERICK MD 217029242	☐ FOB ORIGIN ☒ OTHER (See below)			

CODE	FACILITY CODE

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
5601 Fishers Lane Rockville, MD 208 5601 Fishers Lane Rockville MD 20852	5601 FL	Approved By, NCI Branch D Invoices Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500	NCI INV-BR-D

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304 (c) ( ) ☒ 41 U.S.C. 3304 (a) (3)	See Schedule

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				

15G. TOTAL AMOUNT OF CONTRACT ▶ $6,680,834.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	6
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	4	X	J	LIST OF ATTACHMENTS	10
X	D	PACKAGING AND MARKING	4			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
X	E	INSPECTION AND ACCEPTANCE	4		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	4				
X	G	CONTRACT ADMINISTRATION DATA	5		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	H	SPECIAL CONTRACT REQUIREMENTS	6		M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* 1 *copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ SEALED-BID AWARD (*Contractor is not required to sign this document.)* Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
Connie Suders, Principal Contracts Administrator	SCOTT P. KEASEY

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
Connie E. Suders Digitally signed by Connie E. Suders -S (Affiliate) Date: 2020.04.01 18:35:35 -04'00' BY -S (Affiliate) *(Signature of person authorized to sign)*	April 01, 2020	Scott P. Keasey -S Digitally signed by Scott P. Keasey -S Date: 2020.04.01 19:15:12 -04'00' BY *(Signature of the Contracting Officer)*	

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

STANDARD FORM 26 (Rev. 3/2013)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR

LEIDOS BIOMEDICAL RESEARCH, INC.:1107088

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 04/03/2020 to 04/02/2025				
1	75N91019D00024;75N91020F00010;600.010.77.01;NIAID-DMID-DMID;CVD Preparedness and Response Supplemental Appropriations Act 2020 Delivery To: 5601 FL Product/Service Code: M1HA Product/Service Description: OPERATION OF GOVERNMENT-OWNED CONTRACTOR-OPERATED (GOCO) R&D FACILITIES Project Data: 150809.2020.400.COVID19.THERP.HNM5 NIAID DMID DIV MICROBIOLOGY & INFECTIOUS DISEASES.25505 RESEARCH AND DEVELOPMENT.03/19/2020 Accounting Info: 08019720205DAD.2020.01.M100.HNM1000000C.E.00066.406.NCOV.25505.61000001.9999.9999.9999 Funded: $6,680,834.00				6,680,834.00

In addition to all applicable terms and conditions of the Base Contract 75N91019D00024, the following ARTICLES are also applicable to this task order.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS
ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES
NIAID DMID: COVID-19 Remdesivir Study

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $*TBD*.
b. The fixed fee for this contract is $*TBD*. The fixed fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of The NCI FFRDC Contract.
c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $*TBD*.

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. Task Order Number Designation
On all correspondence submitted under this Task Order, the Contractor agrees to clearly identify the Task Order and contract numbers that appear on the face page of the contract as follows:

Task Order No.: *75N91020F00010*
Contract No.: 75N91019D00024

b. Advance Payment
An advance payment in the amount of $TBD has been negotiated for this task order. The entirety of the advance payment provided from this order shall be repaid against this order.

c. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS
Other provisions of this task order notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. Subcontracts
A Subcontracting ceiling of $ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to: 1) exceed this ceiling or 2) enter into foreign or legal services subcontracts.
b. Consultants
A Consultants ceiling of $ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required for all consultant agreements and modifications to consultant agreements related to cost or scope.
c. Accountable Government Property (Capitalized Equipment)
An Accountable Government Property (Capitalized Equipment) ceiling of $ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to exceed this ceiling.
d. Travel

A Travel ceiling of $ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to: 1) to exceed this ceiling or 2) for all foreign travel. All travel costs exceeding those authorized under the Federal Travel Regulations (FTR) must be justified in writing to the Contracting Officer for Contracting Officer Authorization.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, dated TBD, set forth in SECTION J-List of Attachments, attached hereto and made a part of this Task Order.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only.
All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973.
Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Reporting requirements TBD.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this Task Order other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of materials and services to be provided.
b. Inspection and acceptance will be performed as identified in the NCI FFRDC Bridge Contract for contract-wide requirements and per task order for specific task order requirements.
   Inspection and acceptance for Reporting Requirements will be performed at (via) unless otherwise specified in the Task Order:

   National Cancer Institute at Frederick
   FFRDC Contract Administration System
   https://fcas.nci.nih.gov

   The Government reserves the right to an Inspection period of 30 calendar days. The receiving report constitutes acceptance. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this task order is April 3, 2020 through April 02, 2025.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final task order shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this task order and upon delivery and acceptance by

the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this task order will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

Item	Task Order Article	Description	Delivery Schedule
TBD	TBD	TBD	TBD

b. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No.
Delivered to the Contracting Officer and COR through the FFRDC Contract Administration System (FCAS)	TBD

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Seema Nayak

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this task order; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this task order; (5) otherwise change any terms and conditions of this task order; or (6) sign written licensing agreements.

The Government may unilaterally change its COR designation.

ARTICLE G.2. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this task order is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or task orders (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this task order. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the task order to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100% across all task orders.

TBD

Primary Program Manager

ARTICLE G.3. INVOICE SUBMISSION

In addition to the requirements specified in the base contract 75N91019D00024 and FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

a. The Contract Title is: The NCI FFRDC Bridge Contract
b. The Task Order Title is: NIAID DMID: COVID-19 Remdesivir Study
c. Task Order Line Items are as follows:

PRISM Line Item #	Line Item Description/Project ID	IC	CAN (with Fiscal Year)	CAN Label	Amount	End Date of Funds Availability
1	75N91020F00010; 75N91019D00024; 600.010.77.01; NIAID-DMID-DMID; CVD Preparedness and Response Supplemental Appropriations Act 2020	NIAID	0-8044363	Appropriated	$6,680,834.00	04/02/2025

SECTION H - ADDITONAL CONTRACT CLAUSES

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH & DEVELOPMENT CONTRACT

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. **Alternate I** (April 1984) of FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), is hereby deleted in its entirety and **Alternate V** (April 1984), is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This contract incorporates the following clauses in full text.

1. **FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)**
The Contractor shall indicate acceptance of this letter contract by signing One Copy of the contract and returning them to the Contracting Officer not later than April 3, 2020, 3:00PM EST. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. **FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)**

(a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding $6,680,834.00 dollars.

(b) The maximum amount for which the Government shall be liable if this contract is terminated is $6,680,834.00 dollars.

3. **FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)**

(a) A Cost Plus Fixed Fee definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Cost Plus Fixed Fee proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

(b) The schedule for definitizing this contract is:

Defintization Schedule
a. Statement of Work Review 3-26-2020 - 4-01-2020
b. Issuance of Letter Contract 4-03-2020
c. Letter Contract Post Award Kick Off meeting 4-08-2020
d. Contractor Price Proposal Submittal 5-06-2020
e. POTQ/Technical Review 5-06-2020 - 5-15-2020
f. Negotiations Start 5-18-2020 - 5-22-2020
g. Request Certificate of Current Cost and/or Pricing 5-25-2020
h. Definitization of Letter Contract 5-25-2020 - 6-05-2020

(c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by-

(i) All clauses required by the FAR on the date of execution of this letter contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this letter contract shall continue in effect, except those that by their nature apply only to a letter contract.

4. FAR 52.216-26 - PAYMENTS OF ALLOWABLE COSTS BEFORE DEFINITIZATION (DEC 2002)

(a) Reimbursement rate. Pending the placing of the definitive contract referred to in this letter contract, the Government will promptly reimburse the Contractor for all allowable costs under this contract at the following rates:

(1) One hundred percent of approved costs representing financing payments to subcontractors under fixed-price subcontracts, provided that the Government's payments to the Contractor will not exceed 80 percent of the allowable costs of those subcontractors.

(2) One hundred percent of approved costs representing cost-reimbursement subcontracts; provided, that the Government's payments to the Contractor shall not exceed 85 percent of the allowable costs of those subcontractors.

(3) Eighty-five percent of all other approved costs.

(b) Limitation of reimbursement. To determine the amounts payable to the Contractor under this letter contract, the Contracting Officer shall determine allowable costs in accordance with the applicable cost principles in part 31 of the Federal Acquisition Regulation (FAR). The total reimbursement made under this paragraph shall not exceed 85 percent of the maximum amount of the Government's liability, as stated in this contract.

(c) Invoicing. Payments shall be made promptly to the Contractor when requested as work progresses, but (except for small business concerns) not more often than every 2 weeks, in amounts approved by the Contracting Officer. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost incurred by the Contractor in the performance of this contract.

(d) Allowable costs. For the purpose of determining allowable costs, the term "costs" includes-

(1) Those recorded costs that result, at the time of the request for reimbursement, from payment by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(2) When the Contractor is not delinquent in payment of costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for-

(i) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made-

(A) In accordance with the terms and conditions of a subcontract or invoice; and

(B) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government;

(ii) Materials issued from the Contractor's stores inventory and placed in the production process for use on the contract;

(iii) Direct labor;

(iv) Direct travel;

(v) Other direct in-house costs; and

(vi) Properly allocable and allowable indirect costs as shown on the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(3) The amount of financing payments that the Contractor has paid by cash, check, or other forms of payment to subcontractors.

(e) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(f) Audit. At any time before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of costs audited. Any payment may be-

(1) Reduced by any amounts found by the Contracting Officer not to constitute allowable costs; or

(2) Adjusted for overpayments or underpayments made on preceding invoices or vouchers.

5. ---**Alternate I of 52.222-26** with the following fill in: "The following terms of this clause are waived for this contract: subparagraph (c)(2), (c)(3), (c)(4), (c)(5)(ii), (c)(6), (c)(8), and the phrase "on-site compliance evaluations and" in (c)(9)."

6. ---**Alternate I of 52.222-35** with the following fill in: "The following terms of this clause are waived for this contract: in subparagraph (b), the phrase "and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans"; additionally, in subparagraph (b), the phrase "requirements of the equal opportunity clause at 41CFR 60-300.5(a)" shall be interpreted to exclude in full paragraphs 2-7, 9-10, and12 of 41 CFR 60-300.5(a), and the phrase "take affirmative action to employ, advance in employment and otherwise" from paragraph 1 of 41 CFR 60-300.5(a)."

7. ---**Alternate I of 52.222-36** with the following fill in: "The following terms of this clause are waived for this contract: in subparagraph (a), the phrase “and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities”; additionally, in subparagraph (a), the phrase “requirements of the equal opportunity clause at 41 CFR 60-741.5(a)” shall be interpreted to exclude in full paragraphs 4-5 and 7 of 41 CFR 60-741.5(a), and the phrase “take affirmative action to employ and advance in employment individuals with disabilities, and to “from paragraph 1 of 41 CFR 60-741.5(a)."

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS SECTION J LIST OF ATTACHMENTS

1. Statement of Work

National Institute of Allergy and Infectious Diseases

Division of Microbiology and Infectious Diseases

Non-Severable Task Order

COVID19 Trial

March 2020

1. INTRODUCTION

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID) strives to understand, treat, and ultimately prevent the myriad of infectious, immunologic, and allergic diseases threatening the health of millions of people in the United States and around the world. Against a background of established infections, epidemics of new and old infectious diseases periodically emerge. This threat has been increasingly recognized over the last decade. Emerging/re-emerging and related respiratory viruses causing disease, such as SARS, influenza, and MERS-CoV are of particular concern given their significant morbidity and potential for rapid geographic spread. This objective supports the overall goal to better understand the diseases and therapeutic options and to improve medical outcomes for patients afflicted with the emerging and re-emerging and related respiratory viruses.

1.1 Background

The National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID), rapidly deploys resources to meet the external demands placed on NIAID to facilitate the conduct of time sensitive, high priority, global, collaborative clinical research critical to the mission of the NIAID and advancement of the National Institutes of Health (NIH) and Department of Health & Human Services (DHHS) Global Health Agendas. Fulfillment of this mission requires DMID to have the capacity to expeditiously support collaborative clinical research and conduct clinical trials both domestically and internationally.

In December 2019, the Wuhan Municipal Health Committee identified an outbreak of viral pneumonia cases of unknown cause. Coronavirus RNA was quickly identified in some of these patients. This novel coronavirus has been designated SARS-CoV-2, and the disease caused by this virus has been designated COVID-19. There were 59 confirmed cases on January 5, 2020, 278 cases on January 20, 2118 cases on January 26, rising to more than 64,000 confirmed cases and 1300 deaths as of February 14, 2020 according to various international health reporting agencies. Currently there are no approved therapeutic or prophylactic agents available for coronaviruses.

The objective of this COVID Task Order supports NIAID's goal to better understand the Coronavirus.

DMID is requesting the services of Leidos Biomedical Research, Inc. (LBR) to initiate the management , oversight , and conduct of the NIAID DMID clinical trial titled "A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19" ("Trial"). This study is an adaptive, randomized, double-blind, placebo-controlled trial to

evaluate the safety and efficacy of novel therapeutic agents in hospitalized adult patients diagnosed with COVID-19. The study is a multicenter trial that will be conducted in up to 60 sites globally. The study will compare different investigational therapeutic agents to a placebo. There will be interim monitoring to introduce new arms and allow early stopping for futility, efficacy, or safety. If one therapy proves to be efficacious, this treatment will then become the control arm for comparison(s) with new experimental treatment(s). Because of the possibility that background standards of supportive care may evolve/improve over time as more is learned about successful management of COVID-19, comparisons of safety and efficacy will be based on data from concurrently randomized participants. An independent data and safety monitoring board (DSMB) will actively monitor interim data to make recommendations about early study closure or changes to study arms.

There is no benefit to NIAID until the completion and closeout of the study contemplated hereunder.

Business Assumptions are outlined under Appendix A.

2. Statement of Work

Under this Task Order, LBR shall provide the full range of services required to support DMID in conducting the Trial contemplated hereunder including, but not necessarily limited to, those listed in this Section 2.

2.1 Technical Support and Administrative Management Services

DMID requires LBR to provide the broad range of technical support and administrative management services and program- dedicated research support required to conduct the Trial domestically and internationally as requested.

LBR will establish and maintain a Coordinating Center (CC) to support the Trial with a primary base of operations co-located with NIAID at 5601 Fishers Lane, Rockville, MD.

While not intended to be an exhaustive list of the CC responsibilities, the CC will:

A. Assist the sites in developing, implementing, and monitoring the scientific agenda.
B. Develop agenda and provide logistical support for trial related meetings.
C. Coordinate the development, dissemination, implementation, and update of Manual of Operations and other protocol related documents.
D. Coordinate, develop and disseminate protocols and amendments.
E. Provide translation support of these documents as needed.
F. Coordinate and administer research activities including, but not limited to the following:
    - Support the laboratories, and protocol teams;
    - Maintain administrative records and archives;

- Coordinate trial related workshops, meetings and conference calls;
- Prepare administrative and scientific reports.

G. Develop and maintain a web-based system for dissemination of information.
H. Provide regulatory guidance to investigators and coordinate training of staff at trial sites
I. Assure adherence to internationally mandated ethical and Good Clinical Practice requirements regarding conduct of research involving human subjects.
J. Coordinate and track the publication of Network study results.
K. Coordinate and support preparation of manuscript and scientific presentations.
L. Coordinate and administer training activities needed for the trial.
M. Support sites during trial conduct to include maintaining a 24/7 help line / help desk to rapidly respond to inquiries about the study from participating sites.
N. Gather evaluation data to evaluate site performance.
O. Provide pharmacy guidance and oversight to sites and protocol teams including importation of study drugs.
P. Coordinate and provide procurement support for sites and laboratories.
Q. Provide Information Technology guidance to sites to enhance wide communication and data transfer activities.
R. Track enrollment to studies .
S. Provide guidance to sites on interfacing with the NIAID Statistical and Data Coordinating Center (SDCC) and Clinical Agent Repositories (CAR) for the study.
T. Coordinate and support the development of laboratory capacity if needed.
U. Support the distribution and shipment of specimens.
V. Coordinate documents collection from sites to the Sponsor NIAID.
W. Support the sites submission to regulatory authorities .
X. Perform other duties as required and/or requested by NIAID to ensure optimal coordination of the multi-site, multi-county COVID19 clinical trial.

In DMID's opinion FHI360 is a vendor that is well suited to perform the CC requirements under this YT given their expansive operations domestically and globally; proven track record implementing complex clinical research protocol; and having served as the Network Coordinating Center for NIAID DCR's Special Project – SEAICRN as a subcontractor under LBR.

2.2 Conduct Broad Range of Research

DMID requires LBR to provide other services and additional scientific disciplines as required to facilitate the management and conduct of the Trial contemplated hereunder.

DMID is requesting that LBR furnish all necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to implement the Trial, while ensuring that tasks are conducted in accordance with all applicable and current country, federal, state, and local laws, codes, ordinances and regulations.

While not intended to be an exhaustive list, requirements include:

A. Administrative, Project Management and Overall Support for all Clinical Site Activities
    1. Manage and provide oversight of the Task Order and Subcontractor.
    2. Maintain frequent communications and updates with the COR on the status of the Task Order Activities

B. Clinical Site Identification, Site Readiness and Start-up Activities Prior to Protocol Implementation
The Contractor shall implement, conduct, complete and provide oversight of the clinical study protocol at up to 60 sites. It is anticipated sites are identified mainly from NIAID, but also from contractor, or other collaborators.

For sites the contractor (directly or through operations center) should:
    1. Distribute and collect a clinical site assessment utilizing the NIAID Site Questionnaire (Attachment A).
    2. Participate in a Site Assessment and/or Site Initiation Visit(s) in conjunction with the NIAID Monitoring Contractor in person or by teleconference. Site Initiation may be done via teleconference or in person, at the sponsors discretion.
    3. Assist the site in obtaining initial IRB/IEC, local regulatory authority (as applicable), and other local/institutional approvals as needed, including amendments.
    4. Assist in the preparation of regulatory documentation.
    5. Negotiate and execute all site budgets with Contract Officer approval.
    6. Manage clinical sites in accordance with the Protocol and Manual of Procedures.
    7. Support, if requested, monitoring or audits of clinical trial sites and vendors.
    8. Manage investigator site payments, vendor payments, and other indirect/direct costs per contract and budget.

The sites should
    1. Perform all clinical study procedures as described in the Protocol, the Manual of Procedures, Quality Management Plan, Pharmacy Manual and relevant Standard Operating Procedures.
    2. Perform laboratory analysis of samples as specified in the Protocol and in accordance with cGLP and cGCP regulations and in compliance with domestic and non-domestic laws and regulations.
    3. Recruit and retain the study population as defined in the Protocol.
    4. Identify potential problems associated with conducting this trial including but not limited to those related to recruitment, retention and implement risk mitigation strategies.
    5. Maintain study records (Source Documentation Standards)
        - Documentation of source data should be in compliance with federal, state, local, institutional and international clinical research policies, and consistent with the NIAID NIAID Source Documentation Standards.
        - In carrying out the Protocol, the Contractor is required to maintain regulatory records in accordance with federal, state, local, institutional, and international clinical research policies, and consistent with the NIAID NIAID Regulatory File Document Guidelines).
    6. Data Management and Quality Control

- The Contractor shall collect study data and transfer (direct transfer, completion of CRF, etc. as appropriate) all clinical and laboratory study data to the NIAID SDCC system within seventy-two (72) hours of study visit procedures or activity as defined in the Manual of Procedures, in accordance with the Protocol.
- Participate in data cleaning activities with the site and the SDCC.

7. Study Agents
   - Receive, inventory, store, and dispose/return (unused study agent) study product as specified by NIAID.
8. Regulatory Requirements
   - Maintain IRB/IEC approval, in addition to local regulatory authority approvals, and other local/institutional approvals as needed for amendments and other clinical research modifications.
   - Provide IRB approval documentation per NIAID-CROMS
9. Safety Reporting
   - Report SAEs in the timeframe specified in the protocol.
   - Provide safety follow-up information to NIAID-CROMS as referenced in the Protocol.

C. Clinical Site Training
   1. Assist Clinical Sites with Protocol Specific Training to include training documents posted on the NIAID SDCC Contractors website and ensure site staff have completed the appropriate training for their roles.
   2. Provide GCP and/or HSP Training as needed to Clinical Site Staff in accordance with NIH Requirements.
   3. Assist sites in navigating other study specific training for data management and study product ordering.

D. Protocol Implementation, Conduct, Completion, Analysis and Oversight
   1. Protocol Specific Meeting and Teleconference Support.
   2. Provide for and participate in Protocol specific meeting and teleconference support.
   3. Prepare and distribute meeting and teleconference related materials at least 1 day in advance of all teleconferences. Prepare meeting or teleconferences minutes within 5 calendar days of the meeting or teleconference.
   4. Participate in close-out related meetings/teleconferences for the sites and the clinical study. Participate with the site and the SDCC in all data cleaning activities.
   5. In coordination with the Protocol Team, prepare a manuscript of the primary study results suitable for submission to a peer-reviewed scientific journal.
   6. Arrange and participate in an End of Study Results Dissemination Face-To-Face Meeting.

E. Virology testing
   1. Identify, manage, and provide payment for a laboratory capable of processing the virologic endpoints of the protocol:
      - Qualitative and quantitative PCR for SARS-CoV-2 in OP swab
      - Qualitative and quantitative PCR for SARS-CoV-2 in blood

At the conclusion of the program, a consolidated final report shall be submitted to NIAID DMID summarizing accomplishments, outcomes, and impact on the overall research initiative to improve medical outcomes for patients.

Appendix A

Business Assumptions

A. Study

1. Initial sample size is 440 subjects (includes 10% lost to follow-up). Additional enrollment may be required. This number may be increased up to 709 based upon the true odds ratio or it may also be increased if additional therapeutic arms are added.

B. Coordinating Center

2. Ten FTE equivalents (five 100% FTE, and others with split responsibilities) - some co-located within NIAID at 5601 Fishers Lane, Rockville, MD and some located at an international location.
3. Travel – (2) persons traveling to each site two times per year

C. Sites

1. Up to 100 sites based domestically and internationally, of which the Contractor may be asked to fund up to 70 sites
2. International locations may include sites in:
    1) South Korea
    2) Singapore
    3) Thailand
    4) Japan
    5) Italy
    6) United Kingdom
    7) Other countries may be added

3. Per Site Reimbursement
    1) $10k site initiation fee
    2) $20k per subject enrolled
    3) $10k per year for site principal investigator and staff time to maintain the study regulatory files, IRB continuing reviews, etc.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 10

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00001	See Block 16C	5701719	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
National Institutes of Health National Cancer Institute Bldg 1050 Frederick, MD 21702	NCI-BLDG 427	National Institutes of Health National Cancer Institute Bethesda, MD 20892-7511	NCI

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
LEIDOS BIOMEDICAL RESEARCH, INC.:1107088 P.O. BOX B FREDERICK MD 217029242	(x)	9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75N91019D00024 75N91020F00010
		10B. DATED *(SEE ITEM 13)* 04/01/2020
CODE / FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER If by virtue of this amendment you desire to change an offer already submitted , such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Schedule

Net Increase: $10,104,139.00

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103(a).
	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor ☐ is not. ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

The purpose of this modification is to provide supplemental funding in the amount of $10,104,139 for revisions to the Statement of Work. The total obligated value of this task order increases from $6,680,834 by $10,104,139 to $16,784,973. The total ultimate value of this task order increases from $6,680,834 by $10,104,139 to $16,784,973. This modification also changes the Contracting Officer's Representative (COR). ARTICLE G.1., ARTICLE G.3., ARTICLE I.4., SECTION J., and the Statement of Work are revised.

Period of Performance: 04/03/2020 to 04/02/2025

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Lynn M. Briscoe, Sr. Contracts Manager	SCOTT P. KEASEY

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
Lynn M. Briscoe *(Signature of person authorized to sign)*	05/04/2020	Scott P. Keasey -S *(Signature of Contracting Officer)*	Digitally signed by Scott P. Keasey -S Date: 2020.05.04 12:38:59 -04'00'

NAME OF OFFEROR OR CONTRACTOR
LEIDOS BIOMEDICAL RESEARCH, INC.:1107088

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Delivery: 04/02/2025 Delivery Location Code: 5601 FL 5601 Fishers Lane Rockville, MD 208 5601 Fishers Lane Rockville MD 20852 US Payment: Approved By, NCI Branch D Invoices Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500 Period of Performance: 04/03/2020 to 04/02/2025 Add Item 2 as follows:				
2	75N91020F00010; 75N91019D00024; 600.010.77.01; NIAID-DMID-DMID; CVD Preparedness and Response Supplemental Appropriations Act 2020 Delivery To: 5601 FL Product/Service Code: M1HA Product/Service Description: OPERATION OF GOVERNMENT-OWNED CONTRACTOR-OPERATED (GOCO) R&D FACILITIES Project Data: 150809.2020.400.COVID19.THERP.HNM5 NIAID DMID DIV MICROBIOLOGY & INFECTIOUS DISEASES.25505 RESEARCH AND DEVELOPMENT.04/29/2020 Accounting Info: 08019720205DAD.2020.01.M100.HNM1000000C.E.00066.406.NCOV.25505.61000001.9999.9999.9999 Funded: $10,104,139.00				10,104,139.00

In addition to all applicable terms and conditions of the Base Contract 75N91019D00024, the following ARTICLES are also applicable to this task order.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS
ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES
NIAID DMID: COVID-19 Remdesivir Study

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $*TBD*.
b. The fixed fee for this contract is $*TBD*. The fixed fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of The NCI FFRDC Contract.
c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $*TBD*.

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. Task Order Number Designation
On all correspondence submitted under this Task Order, the Contractor agrees to clearly identify the Task Order and contract numbers that appear on the face page of the contract as follows:

Task Order No.: *75N91020F00010*
Contract No.: 75N91019D00024

b. Advance Payment
An advance payment in the amount of $TBD has been negotiated for this task order. The entirety of the advance payment provided from this order shall be repaid against this order.

c. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS
Other provisions of this task order notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. Subcontracts
A Subcontracting ceiling of $ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to: 1) exceed this ceiling or 2) enter into foreign or legal services subcontracts.
b. Consultants
A Consultants ceiling of $ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required for all consultant agreements and modifications to consultant agreements related to cost or scope.
c. Accountable Government Property (Capitalized Equipment)
An Accountable Government Property (Capitalized Equipment) ceiling of $ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to exceed this ceiling.
d. Travel

A Travel ceiling of $ TBD has been negotiated for this task order. Prior written consent of the Contracting Officer is required to: 1) to exceed this ceiling or 2) for all foreign travel. All travel costs exceeding those authorized under the Federal Travel Regulations (FTR) must be justified in writing to the Contracting Officer for Contracting Officer Authorization.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, dated TBD, set forth in SECTION J-List of Attachments, attached hereto and made a part of this Task Order.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only.
All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973.
Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Reporting requirements TBD.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this Task Order other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of materials and services to be provided.
b. Inspection and acceptance will be performed as identified in the NCI FFRDC Bridge Contract for contract-wide requirements and per task order for specific task order requirements.
   Inspection and acceptance for Reporting Requirements will be performed at (via) unless otherwise specified in the Task Order:

   National Cancer Institute at Frederick
   FFRDC Contract Administration System
   https://fcas.nci.nih.gov

   The Government reserves the right to an Inspection period of 30 calendar days. The receiving report constitutes acceptance. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this task order is April 3, 2020 through April 02, 2025.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final task order shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this task order and upon delivery and acceptance by

the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this task order will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

Item	Task Order Article	Description	Delivery Schedule
TBD	TBD	TBD	TBD

b. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No.
Delivered to the Contracting Officer and COR through the FFRDC Contract Administration System (FCAS)	TBD

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Sonia Gales

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this task order; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this task order; (5) otherwise change any terms and conditions of this task order; or (6) sign written licensing agreements.

The Government may unilaterally change its COR designation.

ARTICLE G.2. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this task order is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or task orders (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this task order. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the task order to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100% across all task orders.

TBD

Primary Program Manager

ARTICLE G.3. INVOICE SUBMISSION

In addition to the requirements specified in the base contract 75N91019D00024 and FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

a. The Contract Title is: The NCI FFRDC Bridge Contract
b. The Task Order Title is: NIAID DMID: COVID-19 Remdesivir Study
c. Task Order Line Items are as follows:

PRISM Line Item #	Line Item Description/Project ID	IC	CAN (with Fiscal Year)	CAN Label	Amount	End Date of Funds Availability
1	75N91020F00010; 75N91019D00024; 600.010.77.01; NIAID-DMID-DMID; CVD Preparedness and Response Supplemental Appropriations Act 2020	NIAID	0-8044363	Appropriated	$6,680,834.00	04/02/2025
2	75N91020F00010; 75N91019D00024; 600.010.77.01; NIAID-DMID-DMID; CVD Preparedness and Response Supplemental Appropriations Act 2020	NIAID	0-8044363	Appropriated	$10,104,139.00	04/02/2025

SECTION H - ADDITONAL CONTRACT CLAUSES

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH & DEVELOPMENT CONTRACT

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. **Alternate I** (April 1984) of FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), is hereby deleted in its entirety and **Alternate V** (April 1984), is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of the contract and returning them to the Contracting Officer not later than April 3, 2020, 3:00PM EST. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding $16,784,973 dollars.

(b) The maximum amount for which the Government shall be liable if this contract is terminated is $16,784,973 dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Cost Plus Fixed Fee definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Cost Plus Fixed Fee proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

(b) The schedule for definitizing this contract is:

Defintization Schedule
a. Statement of Work Review 3-26-2020 - 4-01-2020
b. Issuance of Letter Contract 4-03-2020
c. Letter Contract Post Award Kick Off meeting 4-08-2020
d. Contractor Price Proposal Submittal 5-06-2020
e. POTQ/Technical Review 5-06-2020 - 5-15-2020
f. Negotiations Start 5-18-2020 - 5-22-2020
g. Request Certificate of Current Cost and/or Pricing 5-25-2020
h. Definitization of Letter Contract 5-25-2020 - 6-05-2020

(c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any

event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by-

(i) All clauses required by the FAR on the date of execution of this letter contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this letter contract shall continue in effect, except those that by their nature apply only to a letter contract.

4. FAR 52.216-26 - PAYMENTS OF ALLOWABLE COSTS BEFORE DEFINITIZATION (DEC 2002)

(a) Reimbursement rate. Pending the placing of the definitive contract referred to in this letter contract, the Government will promptly reimburse the Contractor for all allowable costs under this contract at the following rates:

(1) One hundred percent of approved costs representing financing payments to subcontractors under fixed-price subcontracts, provided that the Government's payments to the Contractor will not exceed 80 percent of the allowable costs of those subcontractors.

(2) One hundred percent of approved costs representing cost-reimbursement subcontracts; provided, that the Government's payments to the Contractor shall not exceed 85 percent of the allowable costs of those subcontractors.

(3) Eighty-five percent of all other approved costs.

(b) Limitation of reimbursement. To determine the amounts payable to the Contractor under this letter contract, the Contracting Officer shall determine allowable costs in accordance with the applicable cost principles in part 31 of the Federal Acquisition Regulation (FAR). The total reimbursement made under this paragraph shall not exceed 85 percent of the maximum amount of the Government's liability, as stated in this contract.

(c) Invoicing. Payments shall be made promptly to the Contractor when requested as work progresses, but (except for small business concerns) not more often than every 2 weeks, in amounts approved by the Contracting Officer. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost incurred by the Contractor in the performance of this contract.

(d) Allowable costs. For the purpose of determining allowable costs, the term “costs” includes-

(1) Those recorded costs that result, at the time of the request for reimbursement, from payment by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(2) When the Contractor is not delinquent in payment of costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for-

(i) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made-

(A) In accordance with the terms and conditions of a subcontract or invoice; and

(B) Ordinarily within 30 days of the submission of the Contractor’s payment request to the Government;

(ii) Materials issued from the Contractor’s stores inventory and placed in the production process for use on the contract;

(iii) Direct labor;

(iv) Direct travel;

(v) Other direct in-house costs; and

(vi) Properly allocable and allowable indirect costs as shown on the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(3) The amount of financing payments that the Contractor has paid by cash, check, or other forms of payment to subcontractors.

(e) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(f) Audit. At any time before final payment, the Contracting Officer may have the Contractor’s invoices or vouchers and statements of costs audited. Any payment may be-

(1) Reduced by any amounts found by the Contracting Officer not to constitute allowable costs; or

(2) Adjusted for overpayments or underpayments made on preceding invoices or vouchers.

5. ---**Alternate I of 52.222-26** with the following fill in: "The following terms of this clause are waived for this contract: subparagraph (c)(2), (c)(3), (c)(4), (c)(5)(ii), (c)(6), (c)(8), and the phrase “on-site compliance evaluations and” in (c)(9)."

6. ---**Alternate I of 52.222-35** with the following fill in: "The following terms of this clause are

waived for this contract: in subparagraph (b), the phrase “and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans”; additionally, in subparagraph (b), the phrase “requirements of the equal opportunity clause at 41CFR 60-300.5(a)” shall be interpreted to exclude in full paragraphs 2-7, 9-10, and12 of 41 CFR 60-300.5(a), and the phrase “take affirmative action to employ, advance in employment and otherwise” from paragraph 1 of 41 CFR 60-300.5(a)."

7. ---**Alternate I of 52.222-36** with the following fill in: "The following terms of this clause are waived for this contract: in subparagraph (a), the phrase “and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities”; additionally, in subparagraph (a), the phrase “requirements of the equal opportunity clause at 41 CFR 60-741.5(a)” shall be interpreted to exclude in full paragraphs 4-5 and 7 of 41 CFR 60-741.5(a), and the phrase “take affirmative action to employ and advance in employment individuals with disabilities, and to “from paragraph 1 of 41 CFR 60-741.5(a)."

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS SECTION J LIST OF ATTACHMENTS

1. Statement of Work

National Institute of Allergy and Infectious Diseases

Division of Microbiology and Infectious Diseases

Non-Severable Task Order

COVID19 Trial

March 2020

1. INTRODUCTION

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID) strives to understand, treat, and ultimately prevent the myriad of infectious, immunologic, and allergic diseases threatening the health of millions of people in the United States and around the world. Against a background of established infections, epidemics of new and old infectious diseases periodically emerge. This threat has been increasingly recognized over the last decade. Emerging/re-emerging and related respiratory viruses causing disease, such as SARS, influenza, and MERS-CoV are of particular concern given their significant morbidity and potential for rapid geographic spread. This objective supports the overall goal to better understand the diseases and therapeutic options and to improve medical outcomes for patients afflicted with the emerging and re-emerging and related respiratory viruses.

1.1 Background

The National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID), rapidly deploys resources to meet the external demands placed on NIAID to facilitate the conduct of time sensitive, high priority, global, collaborative clinical research critical to the mission of the NIAID and advancement of the National Institutes of Health (NIH) and Department of Health & Human Services (DHHS) Global Health Agendas. Fulfillment of this mission requires DMID to have the capacity to expeditiously support collaborative clinical research and conduct clinical trials both domestically and internationally.

In December 2019, the Wuhan Municipal Health Committee identified an outbreak of viral pneumonia cases of unknown cause. Coronavirus RNA was quickly identified in some of these patients. This novel coronavirus has been designated SARS-CoV-2, and the disease caused by this virus has been designated COVID-19. There were 59 confirmed cases on January 5, 2020, 278 cases on January 20, 2118 cases on January 26, rising to more than 64,000 confirmed cases and 1300 deaths as of February 14, 2020 according to various international health reporting agencies. Currently there are no approved therapeutic or prophylactic agents available for coronaviruses.

The objective of this COVID Task Order supports NIAID's goal to better understand the Coronavirus.

DMID is requesting the services of Leidos Biomedical Research, Inc. (LBR) to initiate the management , oversight , and conduct of the NIAID DMID clinical trial titled "A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19" ("Trial"). This study is an adaptive, randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of novel therapeutic agents in hospitalized adult patients diagnosed with COVID-19. The study is a multicenter trial that will be conducted in up to 100 sites globally. The study

will compare different investigational therapeutic agents to a placebo. There will be interim monitoring to introduce new arms and allow early stopping for futility, efficacy, or safety. If one therapy proves to be efficacious, this treatment will then become the control arm for comparison(s) with new experimental treatment(s). Because of the possibility that background standards of supportive care may evolve/improve over time as more is learned about successful management of COVID-19, comparisons of safety and efficacy will be based on data from concurrently randomized participants. An independent data and safety monitoring board (DSMB) will actively monitor interim data to make recommendations about early study closure or changes to study arms.

There is no benefit to NIAID until the completion and closeout of the study contemplated hereunder.

Business Assumptions are outlined under Appendix A.

2. Statement of Work

Under this Task Order, LBR shall provide the full range of services required to support DMID in conducting the Trial contemplated hereunder including, but not necessarily limited to, those listed in this Section 2.

2.1 Technical Support and Administrative Management Services

DMID requires LBR to provide the broad range of technical support and administrative management services and program- dedicated research support required to conduct the Trial domestically and internationally as requested.

LBR will establish and maintain a Coordinating Center (CC) to support the Trial with a primary base of operations co-located with NIAID at 5601 Fishers Lane, Rockville, MD.

While not intended to be an exhaustive list of the CC responsibilities, the CC will:

A. Assist the sites in developing, implementing, and monitoring the scientific agenda.
B. Develop agenda and provide logistical support for trial related meetings.
C. Coordinate the development, dissemination, implementation, and update of Manual of Operations and other protocol related documents.
D. Coordinate, develop and disseminate protocols and amendments.
E. Provide translation support of these documents as needed.
F. Coordinate and administer research activities including, but not limited to the following:
    - Support the laboratories, and protocol teams;
    - Maintain administrative records and archives;
    - Coordinate trial related workshops, meetings and conference calls;
    - Prepare administrative and scientific reports.
G. Develop and maintain a web-based system for dissemination of information.
H. Provide regulatory guidance to investigators and coordinate training of staff at trial sites

I. Assure adherence to internationally mandated ethical and Good Clinical Practice requirements regarding conduct of research involving human subjects.
J. Coordinate and track the publication of Network study results.
K. Coordinate and support preparation of manuscript and scientific presentations.
L. Coordinate and administer training activities needed for the trial.
M. Support sites during trial conduct to include maintaining a 24/7 help line / help desk to rapidly respond to inquiries about the study from participating sites.
N. Gather evaluation data to evaluate site performance.
O. Provide pharmacy guidance and oversight to sites and protocol teams including importation of study drugs.
P. Coordinate and provide procurement support for sites and laboratories.
Q. Provide Information Technology guidance to sites to enhance wide communication and data transfer activities.
R. Track enrollment to studies .
S. Provide guidance to sites on interfacing with the NIAID Statistical and Data Coordinating Center (SDCC) and Clinical Agent Repositories (CAR) for the study.
T. Coordinate and support the development of laboratory capacity if needed.
U. Support the distribution and shipment of specimens.
V. Coordinate documents collection from sites to the Sponsor NIAID.
W. Support the sites submission to regulatory authorities .
X. Perform other duties as required and/or requested by NIAID to ensure optimal coordination of the multi-site, multi-county COVID19 clinical trial.

In DMID's opinion FHI360 is a vendor that is well suited to perform the CC requirements under this YT given their expansive operations domestically and globally; proven track record implementing complex clinical research protocol; and having served as the Network Coordinating Center for NIAID DCR's Special Project – SEAICRN as a subcontractor under LBR.

2.2 Conduct Broad Range of Research

DMID requires LBR to provide other services and additional scientific disciplines as required to facilitate the management and conduct of the Trial contemplated hereunder.

DMID is requesting that LBR furnish all necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to implement the Trial, while ensuring that tasks are conducted in accordance with all applicable and current country, federal, state, and local laws, codes, ordinances and regulations.

While not intended to be an exhaustive list, requirements include:

A. Administrative, Project Management and Overall Support for all Clinical Site Activities
    1. Manage and provide oversight of the Task Order and Subcontractor.
    2. Maintain frequent communications and updates with the COR on the status of the Task Order Activities

B. Clinical Site Identification, Site Readiness and Start-up Activities Prior to Protocol Implementation
The Contractor shall implement, conduct, complete and provide oversight of the clinical study protocol at up to 60 sites. It is anticipated sites are identified mainly from NIAID, but also from contractor, or other collaborators.

For sites the contractor (directly or through operations center) should:

1. Distribute and collect a clinical site assessment utilizing the NIAID Site Questionnaire (Attachment A).
2. Participate in a Site Assessment and/or Site Initiation Visit(s) in conjunction with the NIAID Monitoring Contractor in person or by teleconference. Site Initiation may be done via teleconference or in person, at the sponsors discretion.
3. Assist the site in obtaining initial IRB/IEC, local regulatory authority (as applicable), and other local/institutional approvals as needed, including amendments.
4. Assist in the preparation of regulatory documentation.
5. Negotiate and execute all site budgets with Contract Officer approval.
6. Manage clinical sites in accordance with the Protocol and Manual of Procedures.
7. Support, if requested, monitoring or audits of clinical trial sites and vendors.
8. Manage investigator site payments, vendor payments, and other indirect/direct costs per contract and budget.

The sites should

1. Perform all clinical study procedures as described in the Protocol, the Manual of Procedures, Quality Management Plan, Pharmacy Manual and relevant Standard Operating Procedures.
2. Perform laboratory analysis of samples as specified in the Protocol and in accordance with cGLP and cGCP regulations and in compliance with domestic and non-domestic laws and regulations.
3. Recruit and retain the study population as defined in the Protocol.
4. Identify potential problems associated with conducting this trial including but not limited to those related to recruitment, retention and implement risk mitigation strategies.
5. Maintain study records (Source Documentation Standards)
    - Documentation of source data should be in compliance with federal, state, local, institutional and international clinical research policies, and consistent with the NIAID NIAID Source Documentation Standards.
    - In carrying out the Protocol, the Contractor is required to maintain regulatory records in accordance with federal, state, local, institutional, and international clinical research policies, and consistent with the NIAID NIAID Regulatory File Document Guidelines).
6. Data Management and Quality Control
    - The Contractor shall collect study data and transfer (direct transfer, completion of CRF, etc. as appropriate) all clinical and laboratory study data to the NIAID SDCC system within seventy-two (72) hours of study visit procedures or activity as defined in the Manual of Procedures, in accordance with the Protocol.
    - Participate in data cleaning activities with the site and the SDCC.
7. Study Agents
    - Receive, inventory, store, and dispose/return (unused study agent) study product as specified by NIAID.
8. Regulatory Requirements

- Maintain IRB/IEC approval, in addition to local regulatory authority approvals, and other local/institutional approvals as needed for amendments and other clinical research modifications.
- Provide IRB approval documentation per NIAID-CROMS

9. Safety Reporting
   - Report SAEs in the timeframe specified in the protocol.
   - Provide safety follow-up information to NIAID-CROMS as referenced in the Protocol.

C. Clinical Site Training
   1. Assist Clinical Sites with Protocol Specific Training to include training documents posted on the NIAID SDCC Contractors website and ensure site staff have completed the appropriate training for their roles.
   2. Provide GCP and/or HSP Training as needed to Clinical Site Staff in accordance with NIH Requirements.
   3. Assist sites in navigating other study specific training for data management and study product ordering.

D. Protocol Implementation, Conduct, Completion, Analysis and Oversight
   1. Protocol Specific Meeting and Teleconference Support.
   2. Provide for and participate in Protocol specific meeting and teleconference support.
   3. Prepare and distribute meeting and teleconference related materials at least 1 day in advance of all teleconferences. Prepare meeting or teleconferences minutes within 5 calendar days of the meeting or teleconference.
   4. Participate in close-out related meetings/teleconferences for the sites and the clinical study. Participate with the site and the SDCC in all data cleaning activities.
   5. In coordination with the Protocol Team, prepare a manuscript of the primary study results suitable for submission to a peer-reviewed scientific journal.
   6. Arrange and participate in an End of Study Results Dissemination Face-To-Face Meeting.

E. Virology testing
   1. Identify, manage, and provide payment for a laboratory capable of processing the virologic endpoints of the protocol:
      - Qualitative and quantitative PCR for SARS-CoV-2 in OP swab
      - Qualitative and quantitative PCR for SARS-CoV-2 in blood

At the conclusion of the program, a consolidated final report shall be submitted to NIAID DMID summarizing accomplishments, outcomes, and impact on the overall research initiative to improve medical outcomes for patients.

Appendix A

Business Assumptions

A. Study

1. Initial sample size is 440 subjects (includes 10% lost to follow-up). Additional enrollment will be required. This number may be increased up to 1200 based upon the true odds ratio or it may also be increased if additional therapeutic arms are added.

B. Coordinating Center

2. Ten FTE equivalents (five 100% FTE, and others with split responsibilities) - some co-located within NIAID at 5601 Fishers Lane, Rockville, MD and some located at an international location.
3. Travel – (2) persons traveling to each site two times per year

C. Sites

1. Up to 100 sites based domestically and internationally, of which the Contractor may be asked to fund up to 80 sites
2. International locations may include sites in:
    1) South Korea
    2) Singapore
    3) Thailand
    4) Japan
    5) Italy
    6) United Kingdom
    7) Mexico
    8) Other countries may be added

3. Per Site Reimbursement
    1) $10k site initiation fee
    2) $20k per subject enrolled
    3) $10k per year for site principal investigator and staff time to maintain the study regulatory files, IRB continuing reviews, etc.

The Emmes Company, LLC

Billing Number: 000005
Invoice Number: INV-0000010836

Invoice Date: 05/14/2020

Bill To:
National Institutes of Health
Office of Financial Mngt Commercial Acct
2115 East Jefferson St.,RM4B-432,MSC8500
Bethesda, MD 20892-8500

Remit To:
The Emmes Company, LLC
401 N Washington St, Ste 700
Attn: Accounting Department
(301) 251-1161
Rockville, MD 20850

			Funded Value
Customer Number:	N00005	Cost:	$0.00
Prime Contract Number:	HHSN272201500002C	Fee:	$0.00
Subcontractor Number:		Total:	$0.00

Project Number: 13451.00.06.08AX
Project Name: 20-0006 COV ADAPTIVE TX
Project POP: 02/16/2020 to 09/05/2020
Project Manager: Ewell, Marian
Terms: NET 30
Due Date: 06/13/2020
VAT/Tax ID Number: 54-1058268

Cumulative Amount Billed: $1,025,195.94

Billing Period From: 04/01/2020 To: 04/30/2020

Billing Currency: USD

		Current Amount	Cumulative Amount
Direct Labor		Labor Costs	Labor Costs
Total Labor Cost			
Subcontracts		Line Item Costs	Line Item Costs
O/S			
Total Non-Labor Cost			
Fringe	Fringe	Fringe Benefits	Fringe
Overhead	Indirect Cost	Indirect Cost	Indirect Cost
ITCC			
G&A			
SHC/MHC			
Total Indirect Cost			
Fee	Fee	Fee	Fee
Total Fee			
Invoice Total		$611,555.17	$1,025,195.94

Current Incurred Hours:
Cumulative Incurred Hours:

Labor Hours

I certify that all payments requested are for appropriate purposes and in accordance with the contract.

_____
David Jenkins

From: Lee, Marina (NIH/NIAID) [E]
To: Nayak, Seema (NIH/NIAID) [E]
Cc: Gill, Ranjodh (NIH/NIAID) [E]; Sparer, Olivia (NIH/NIAID) [C]
Subject: RE: GAO audit
Date: Friday, May 1, 2020 4:37:57 PM

20-0006		**$ 7,060,938**
Emmes		413,640.76
LG		310098
Sites	BCM	439,280
	Rochester	270,156
	SLU	1607442
	UMD	319,589
	UW	1421433
	VUMC	842642
	Emory	1746755

Non-responsive

From: Sparer, Olivia (NIH/NIAID) [C] <olivia.sparer@nih.gov>
Sent: Friday, 1 May, 2020 3:44 PM
To: Lee, Marina (NIH/NIAID) [E] <marina.lee@nih.gov>; Nayak, Seema (NIH/NIAID) [E] <seema.nayak@nih.gov>
Cc: Gill, Ranjodh (NIH/NIAID) [E] <ranjodh.gill@nih.gov>
Subject: RE: GAO audit
Plus Emmes costs of $644,184.70…
NEW GRAND TOTAL: $11,483,995.70

From: Lee, Marina (NIH/NIAID) [E] <marina.lee@nih.gov>
Sent: Friday, May 1, 2020 3:35 PM
To: Sparer, Olivia (NIH/NIAID) [C] <olivia.sparer@nih.gov>; Nayak, Seema (NIH/NIAID) [E] <seema.nayak@nih.gov>
Cc: Gill, Ranjodh (NIH/NIAID) [E] <ranjodh.gill@nih.gov>
Subject: RE: GAO audit
Additions/revisions:
Totals now reflect all grant funding for these two trials as of today.
Non-responsive
20-0006: $4,900,542 (above) + $1,746,755 (Emory, below from RG) + $310,098 = **$6,957,395**
GRAND TOTAL: $10,839,811

From: Sparer, Olivia (NIH/NIAID) [C] <olivia.sparer@nih.gov>
Sent: Friday, 1 May, 2020 3:03 PM
To: Nayak, Seema (NIH/NIAID) [E] <seema.nayak@nih.gov>
Cc: Lee, Marina (NIH/NIAID) [E] <marina.lee@nih.gov>; Gill, Ranjodh (NIH/NIAID) [E] <ranjodh.gill@nih.gov>
Subject: RE: GAO audit
Hi Seema,
Below please find the totals for the 20-0006 supplements for the six sites you asked me to look up:

BCM: $439,280
Rochester: $270,156
SLU (#s from Ranjodh): $532,714 + $1,074,728 = $1,607,442
UMD: $319,589
UW: $708,920 + $712,513 = $1,421,433
VUMC: $192,338 + $650,304 = $842,642
Total: $4,900,542

So adding up from above/below and the $264K for 20-0003 LG you shared via Skype:
*Marina, is anything missing? LG supplement for 20-0006?

From: Gill, Ranjodh (NIH/NIAID) [E] <ranjodh.gill@nih.gov>
Sent: Friday, May 1, 2020 10:46 AM
To: Nayak, Seema (NIH/NIAID) [E] <seema.nayak@nih.gov>
Cc: Lee, Marina (NIH/NIAID) [E] <marina.lee@nih.gov>; Sparer, Olivia (NIH/NIAID) [C] <olivia.sparer@nih.gov>
Subject: RE: GAO audit
Seema,
Non-responsive
Here are my 20-0006 Sups:
Emory 1: $ 278,570
Emory 2 : $ 1,468,185 (excluding 20-0003 costs) * Approximate Costs
Emory Total: $ 1,746,755
SLU 1: $ 532,714
Proprietary Info
V/r,
Ranjodh